

available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to § 205.303.

(c) *Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."* Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (f)(1), (2), and (3) of § 205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of § 205.301. If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to § 205.304.

(d) *Products with less than 70 percent organically produced ingredients.* The organic ingredients in multiingredient agricultural product containing less than 70 percent organically produced ingredients (by weight or fluid volume, excluding water and salt) must be produced and handled pursuant to requirements in subpart C of this part. The nonorganic ingredients may be produced and handled without regard to the requirements of this part. Multiingredient agricultural product containing less than 70 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.

(e) *Livestock feed.* (1) A raw or processed livestock feed product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product.

(2) A raw or processed livestock feed product sold, labeled, or represented as "organic" must be produced in conformance with § 205.237.

(f) All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not:

(1) Be produced using excluded methods, pursuant to § 201.105(e) of this chapter;

(2) Be produced using sewage sludge, pursuant to § 201.105(f) of this chapter;

(3) Be processed using ionizing radiation, pursuant to § 201.105(g) of this chapter;

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, products labeled as "100 percent organic," if processed, must be processed using organically produced processing aids;

(5) Contain sulfites, nitrates, or nitrites added during the production or handling process, Except, that, wine containing added sulfites may be labeled "made with organic grapes";

(6) Be produced using nonorganic ingredients when organic ingredients are available; or

(7) Include organic and nonorganic forms of the same ingredient.

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.

(c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

§ 205.303 Packaged products labeled "100 percent organic" or "organic."

(a) Agricultural products in packages described in § 205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following:

(1) The term, "100 percent organic" or "organic," as applicable, to modify the name of the product;

(2) For products labeled "organic," the percentage of organic ingredients in the product; (The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.)

(3) The term, "organic," to identify the organic ingredients in multiingredient products labeled "100 percent organic";

(4) The USDA seal; and/or

(5) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, the handler producing the finished product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: *Provided further*, That, such seals or marks are not individually displayed more prominently than the USDA seal.

(b) Agricultural products in packages described in § 205.301(a) and (b) must:

(1) For products labeled "organic," identify each organic ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by * * *," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.

§ 205.304 Packaged products labeled “made with organic (specified ingredients or food group(s)).”

(a) Agricultural products in packages described in § 205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product:

(1) The statement:

(i) “Made with organic (specified ingredients)”: *Provided*, That, the statement does not list more than three organically produced ingredients; or

(ii) “Made with organic (specified food groups)”: *Provided*, That, the statement does not list more than three of the following food groups: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products; and, *Provided further*, That, all ingredients of each listed food group in the product must be organically produced; and

(iii) Which appears in letters that do not exceed one-half the size of the largest type size on the panel and which appears in its entirety in the same type size, style, and color without highlighting.

(2) The percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.

(3) The seal, logo, or other identifying mark of the certifying agent that certified the handler of the finished product.

(b) Agricultural products in packages described in § 205.301(c) must:

(1) In the ingredient statement, identify each organic ingredient with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product: *Except*, That, the business address, Internet address, or telephone number of the certifying agent may be included in such label.

(c) Agricultural products in packages described in § 205.301(c) must not display the USDA seal.

§ 205.305 Multi-ingredient packaged products with less than 70 percent organically produced ingredients.

(a) An agricultural product with less than 70 percent organically produced ingredients may only identify the organic content of the product by:

(1) Identifying each organically produced ingredient in the ingredient statement with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced, and

(2) If the organically produced ingredients are identified in the ingredient statement, displaying the product’s percentage of organic contents on the information panel.

(b) Agricultural products with less than 70 percent organically produced ingredients must not display:

(1) The USDA seal; and

(2) Any certifying agent seal, logo, or other identifying mark which represents organic certification of a product or product ingredients.

§ 205.306 Labeling of livestock feed.

(a) Livestock feed products described in § 205.301(e)(1) and (e)(2) may display on any package panel the following terms:

(1) The statement, “100 percent organic” or “organic,” as applicable, to modify the name of the feed product;

(2) The USDA seal;

(3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the raw or processed organic ingredients used in the finished product, *Provided*, That, such seals or marks are not displayed more prominently than the USDA seal;

(4) The word, “organic,” or an asterisk or other reference mark which is defined on the package to identify ingredients that are organically produced. Water or salt included as ingredients cannot be identified as organic.

(b) Livestock feed products described in § 205.301(e)(1) and (e)(2) must:

(1) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.

(2) Comply with other Federal agency or State feed labeling requirements as applicable.

§ 205.307 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”

(a) Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

(1) The name and contact information of the certifying agent which certified the handler which assembled the final product;

(2) Identification of the product as organic;

(3) Special handling instructions needed to maintain the organic integrity of the product;

(4) The USDA seal;

(5) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.

(b) Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable.

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: *Provided*, That, the shipping containers and shipping documents accompanying such organic products are clearly marked “For Export Only” and: *Provided further*, That, proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt and excluded operations under § 205.101.

§ 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “100 percent organic” or “organic.”

(a) Agricultural products in other than packaged form may use the term, “100 percent organic” or “organic,” as applicable, to modify the name of the product in retail display, labeling, and display containers: *Provided*, That, the term, “organic,” is used to identify the organic ingredients listed in the ingredient statement.

(b) If the product is prepared in a certified facility, the retail display, labeling, and display containers may use:

(1) The USDA seal; and

(2) The seal, logo, or other identifying mark of the certifying agent that

certified the production or handling operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, such seals or marks are not individually displayed more prominently than the USDA seal.

§ 205.309 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as “made with organic (specified ingredients or food group(s)).”

(a) Agricultural products in other than packaged form containing between 70 and 95 percent organically produced ingredients may use the phrase, “made with organic (specified ingredients or food group(s)),” to modify the name of the product in retail display, labeling, and display containers.

(1) Such statement must not list more than three organic ingredients or food groups, and

(2) In any such display of the product’s ingredient statement, the organic ingredients are identified as “organic.”

(b) If prepared in a certified facility, such agricultural products labeled as “made with organic (specified ingredients or food group(s))” in retail displays, display containers, and market information may display the certifying agent’s seal, logo, or other identifying mark.

§ 205.310 Agricultural products produced on an exempt or excluded operation.

(a) An agricultural product organically produced or handled on an exempt or excluded operation must not:

(1) Display the USDA seal or any certifying agent’s seal or other identifying mark which represents the exempt or excluded operation as a certified organic operation, or

(2) Be represented as a certified organic product or certified organic ingredient to any buyer.

(b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multiingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as “organic” in a product processed by others.

(c) Such product is subject to requirements specified in paragraph (a) of § 205.300, and paragraphs (f)(1) through (f)(7) of § 205.301.

§ 205.311 USDA Seal.

(a) The USDA seal described in paragraphs (b) and (c) of this section

may be used only for raw or processed agricultural products described in paragraphs (a), (b), (e)(1), and (e)(2) of § 205.301.

(b) The USDA seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:

(1) On a white background with a brown outer circle and with the term, “USDA,” in green overlaying a white upper semicircle and with the term, “organic,” in white overlaying the green lower half circle; or

(2) On a white or transparent background with black outer circle and black “USDA” on a white or transparent upper half of the circle with a contrasting white or transparent “organic” on the black lower half circle.

(3) The green or black lower half circle may have four light lines running from left to right and disappearing at the point on the right horizon to resemble a cultivated field.



Figure 1

§§ 205.312–205.399 [Reserved]

Subpart E—Certification

§ 205.400 General requirements for certification.

A person seeking to receive or maintain organic certification under the regulations in this part must:

(a) Comply with the Act and applicable organic production and handling regulations of this part;

(b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in § 205.200;

(c) Permit on-site inspections with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices by the certifying agent as provided for in § 205.403;

(d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State organic

program’s governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.104;

(e) Submit the applicable fees charged by the certifying agent; and

(f) Immediately notify the certifying agent concerning any:

(1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and

(2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

§ 205.401 Application for certification.

A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information:

(a) An organic production or handling system plan, as required in § 205.200;

(b) The name of the person completing the application; the applicant’s business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant’s behalf;

(c) The name(s) of any organic certifying agent(s) to which application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliances noted in the notification of noncompliance, including evidence of such correction; and

(d) Other information necessary to determine compliance with the Act and the regulations in this part.

§ 205.402 Review of application.

(a) Upon acceptance of an application for certification, a certifying agent must:

(1) Review the application to ensure completeness pursuant to § 205.401;

(2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;

(3) Verify that an applicant who previously applied to another certifying agent and received a notification of

noncompliance or denial of certification, pursuant to § 205.405, has submitted documentation to support the correction of any noncompliances identified in the notification of noncompliance or denial of certification, as required in § 205.405(e); and

(4) Schedule an on-site inspection of the operation to determine whether the applicant qualifies for certification if the review of application materials reveals that the production or handling operation may be in compliance with the applicable requirements of subpart C of this part.

(b) The certifying agent shall within a reasonable time:

(1) Review the application materials received and communicate its findings to the applicant;

(2) Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed; and

(3) Provide the applicant with a copy of the test results for any samples taken by an inspector.

(c) The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

§ 205.403 On-site inspections.

(a) *On-site inspections.* (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.

(2) (i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.

(ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance

with the Act and the regulations in this part.

(iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.

(b) *Scheduling.* (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: *Except*, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

(2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

(c) *Verification of information.* The on-site inspection of an operation must verify:

(1) The operation's compliance or capability to comply with the Act and the regulations in this part;

(2) That the information, including the organic production or handling system plan, provided in accordance with §§ 205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;

(3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

(d) *Exit interview.* The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.

(e) *Documents to the inspected operation.* (1) At the time of the inspection, the inspector shall provide

the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.

(2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.

§ 205.404 Granting certification.

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall grant certification. The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification.

(b) The certifying agent must issue a certificate of organic operation which specifies the:

(1) Name and address of the certified operation;

(2) Effective date of certification;

(3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and

(4) Name, address, and telephone number of the certifying agent.

(c) Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program's governing State official, or the Administrator.

§ 205.405 Denial of certification.

(a) When the certifying agent has reason to believe, based on a review of the information specified in § 205.402 or § 205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification. The notification of noncompliance shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) Upon receipt of such notification of noncompliance, the applicant may:

(1) Correct noncompliances and submit a description of the corrective actions taken with supporting documentation to the certifying agent;

(2) Correct noncompliances and submit a new application to another certifying agent: *Provided*, That, the applicant must include a complete application, the notification of noncompliance received from the first certifying agent, and a description of the corrective actions taken with supporting documentation; or

(3) Submit written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance.

(c) After issuance of a notification of noncompliance, the certifying agent must:

(1) Evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal, conduct an on-site inspection if necessary, and

(i) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to § 205.404; or

(ii) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.

(2) Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.

(3) Provide notice of approval or denial to the Administrator, pursuant to § 205.501(a)(14).

(d) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:

(1) Reapply for certification pursuant to §§ 205.401 and 205.405(e);

(2) Request mediation pursuant to § 205.663 or, if applicable, pursuant to a State organic program; or

(3) File an appeal of the denial of certification pursuant to § 205.681 or, if applicable, pursuant to a State organic program.

(e) An applicant for certification who has received a written notification of noncompliance or a written notice of

denial of certification may apply for certification again at any time with any certifying agent, in accordance with §§ 205.401 and 205.405(e). When such applicant submits a new application to a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance.

(f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to § 205.402.

(g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

§ 205.406 Continuation of certification.

(a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:

(1) An updated organic production or handling system plan which includes:

(i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and

(ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.200;

(2) Any additions to or deletions from the information required pursuant to § 205.401(b);

(3) An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and

(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

(b) Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to § 205.403: *Except*, That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: *Provided*, That, the annual on-site inspection, required pursuant to § 205.403, is conducted within the first 6 months following the certified operation's scheduled date of annual update.

(c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in § 205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with § 205.662.

(d) If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to § 205.404(b).

§§ 205.407–205.499 [Reserved]

Subpart F—Accreditation of Certifying Agents

§ 205.500 Areas and duration of accreditation.

(a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.

(b) Accreditation shall be for a period of 5 years from the date of approval of accreditation pursuant to § 205.506.

(c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:

(1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the

foreign certifying agent meet the requirements of this part; or

(2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.

§ 205.501 General requirements for accreditation.

(a) A private or governmental entity accredited as a certifying agent under this subpart must:

(1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;

(2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart;

(3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;

(4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;

(5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.

(6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;

(7) Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;

(8) Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;

(9) Maintain all records pursuant to § 205.510(b) and make all such records

available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official;

(10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in § 205.504(b)(5);

(11) Prevent conflicts of interest by:

(i) Not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(ii) Excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(iii) Not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected: *Except*, That, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations;

(iv) Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification;

(v) Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report; and

(vi) Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.

(12)(i) Reconsider a certified operation's application for certification and, if necessary, perform a new on-site inspection when it is determined, within 12 months of certifying the operation, that any person participating in the certification process and covered under § 205.501(a)(11)(ii) has or had a conflict of interest involving the applicant. All costs associated with a reconsideration of application, including onsite inspection costs, shall be borne by the certifying agent.

(ii) Refer a certified operation to a different accredited certifying agent for recertification and reimburse the operation for the cost of the recertification when it is determined that any person covered under § 205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant.

(13) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to § 205.500;

(14) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(15) Submit to the Administrator a copy of:

(i) Any notice of denial of certification issued pursuant to § 205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to § 205.662 simultaneously with its issuance; and

(ii) A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year;

(16) Charge applicants for certification and certified production and handling operations only those fees and charges for certification activities that it has filed with the Administrator;

(17) Pay and submit fees to AMS in accordance with § 205.640;

(18) Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for

the correction of minor noncompliances;

(19) Accept all production or handling applications that fall within its area(s) of accreditation and certify all qualified applicants, to the extent of its administrative capacity to do so without regard to size or membership in any association or group; and

(20) Demonstrate its ability to comply with a State's organic program to certify organic production or handling operations within the State.

(21) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private or governmental entity accredited as a certifying agent under this subpart may establish a seal, logo, or other identifying mark to be used by production and handling operations certified by the certifying agent to indicate affiliation with the certifying agent: *Provided, That*, the certifying agent:

(1) Does not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification and

(2) Does not require compliance with any production or handling practices other than those provided for in the Act and the regulations in this part as a condition of use of its identifying mark: *Provided, That*, certifying agents certifying production or handling operations within a State with more restrictive requirements, approved by the Secretary, shall require compliance with such requirements as a condition of use of their identifying mark by such operations.

(c) A private entity accredited as a certifying agent must:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to any applicable State organic program's governing State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation; *Provided, That*, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

(d) No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the National Organic Program to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

§ 205.502 Applying for accreditation.

(a) A private or governmental entity seeking accreditation as a certifying agent under this subpart must submit an application for accreditation which contains the applicable information and documents set forth in §§ 205.503 through 205.505 and the fees required in § 205.640 to: Program Manager, USDA—AMS—TNP—NOP, Room 2945—South Building, P.O. Box 96456, Washington, DC 20090—6456.

(b) Following the receipt of the information and documents, the Administrator will determine, pursuant to § 205.506, whether the applicant for accreditation should be accredited as a certifying agent.

§ 205.503 Applicant information.

A private or governmental entity seeking accreditation as a certifying agent must submit the following information:

(a) The business name, primary office location, mailing address, name of the person(s) responsible for the certifying agent's day-to-day operations, contact numbers (telephone, facsimile, and Internet address) of the applicant, and, for an applicant who is a private person, the entity's taxpayer identification number;

(b) The name, office location, mailing address, and contact numbers (telephone, facsimile, and Internet address) for each of its organizational units, such as chapters or subsidiary offices, and the name of a contact person for each unit;

(c) Each area of operation (crops, wild crops, livestock, or handling) for which accreditation is requested and the estimated number of each type of operation anticipated to be certified annually by the applicant along with a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant;

(d) The type of entity the applicant is (e.g., government agricultural office, for-profit business, not-for-profit membership association) and for:

(1) A governmental entity, a copy of the official's authority to conduct certification activities under the Act and the regulations in this part,

(2) A private entity, documentation showing the entity's status and organizational purpose, such as articles of incorporation and by-laws or ownership or membership provisions, and its date of establishment; and

(e) A list of each State or foreign country in which the applicant currently certifies production and handling operations and a list of each State or foreign country in which the applicant intends to certify production or handling operations.

§ 205.504 Evidence of expertise and ability.

A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§ 205.100 and 205.101, §§ 205.201 through 205.203, §§ 205.300 through 205.303, §§ 205.400 through 205.406, and §§ 205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in § 205.501:

(a) *Personnel.* (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel;

(2) The name and position description of all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent;

(3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:

(i) Each inspector to be used by the applicant and

(ii) Each person to be designated by the applicant to review or evaluate applications for certification; and

(4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.

(b) *Administrative policies and procedures.* (1) A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates;

(2) A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act

and the regulations in this part to the Administrator;

(3) A copy of the procedures to be used for complying with the recordkeeping requirements set forth in § 205.501(a)(9);

(4) A copy of the procedures to be used for maintaining the confidentiality of any business-related information as set forth in § 205.501(a)(10);

(5) A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request:

(i) Certification certificates issued during the current and 3 preceding calendar years;

(ii) A list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years;

(iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years; and

(iv) Other business information as permitted in writing by the producer or handler; and

(6) A copy of the procedures to be used for sampling and residue testing pursuant to § 205.670.

(c) *Conflicts of interest.* (1) A copy of procedures intended to be implemented to prevent the occurrence of conflicts of interest, as described in § 205.501(a)(11).

(2) For all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent, a conflict of interest disclosure report, identifying any food- or agriculture-related business interests, including business interests of immediate family members, that cause a conflict of interest.

(d) *Current certification activities.* An applicant who currently certifies production or handling operations must submit: (1) A list of all production and handling operations currently certified by the applicant;

(2) Copies of at least 3 different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested; and

(3) The results of any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities.

(e) *Other information.* Any other information the applicant believes may assist in the Administrator's evaluation of the applicant's expertise and ability.

§ 205.505 Statement of agreement.

(a) A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including:

(1) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to § 205.500;

(2) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(3) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;

(4) Have an annual internal program review conducted of its certification activities by certifying agent staff, an outside auditor, or a consultant who has the expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part;

(5) Pay and submit fees to AMS in accordance with § 205.640; and

(6) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private entity seeking accreditation as a certifying agent under this subpart must additionally agree to:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying

agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to the applicable State organic program's governing State official all records or copies of records concerning the certifying agent's certification activities in the event that the certifying agent dissolves or loses its accreditation; *Provided*, That such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

§ 205.506 Granting accreditation.

(a) Accreditation will be granted when:

(1) The accreditation applicant has submitted the information required by §§ 205.503 through 205.505;

(2) The accreditation applicant pays the required fee in accordance with § 205.640(c); and

(3) The Administrator determines that the applicant for accreditation meets the requirements for accreditation as stated in § 205.501, as determined by a review of the information submitted in accordance with §§ 205.503 through 205.505 and, if necessary, a review of the information obtained from a site evaluation as provided for in § 205.508.

(b) On making a determination to approve an application for accreditation, the Administrator will notify the applicant of the granting of accreditation in writing, stating:

(1) The area(s) for which accreditation is given;

(2) The effective date of the accreditation;

(3) Any terms and conditions for the correction of minor noncompliances; and

(4) For a certifying agent who is a private entity, the amount and type of security that must be established to protect the rights of production and handling operations certified by such certifying agent.

(c) The accreditation of a certifying agent shall continue in effect until such time as the certifying agent fails to renew accreditation as provided in § 205.510(c), the certifying agent voluntarily ceases its certification activities, or accreditation is suspended or revoked pursuant to § 205.665.

§ 205.507 Denial of accreditation.

(a) If the Program Manager has reason to believe, based on a review of the information specified in §§ 205.503 through 205.505 or after a site evaluation as specified in § 205.508, that an applicant for accreditation is not able to comply or is not in compliance with the requirements of the Act and the regulations in this part, the Program

Manager shall provide a written notification of noncompliance to the applicant. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) When each noncompliance has been resolved, the Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application.

(c) If an applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal of the notification of noncompliance by the date specified, or is unsuccessful in its rebuttal, the Program Manager will provide the applicant with written notification of accreditation denial. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with § 205.502, or appeal the denial of accreditation in accordance with § 205.681 by the date specified in the notification of accreditation denial.

(d) If the certifying agent was accredited prior to the site evaluation and the certifying agent fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, or fails to file a rebuttal of the notification of noncompliance by the date specified, the Administrator will begin proceedings to suspend or revoke the certifying agent's accreditation. A certifying agent who has had its accreditation suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

§ 205.508 Site evaluations.

(a) Site evaluations of accredited certifying agents shall be conducted for

the purpose of examining the certifying agent's operations and evaluating its compliance with the Act and the regulations of this part. Site evaluations shall include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. Site evaluations shall be conducted by a representative(s) of the Administrator.

(b) An initial site evaluation of an accreditation applicant shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." A site evaluation shall be conducted after application for renewal of accreditation but prior to the issuance of a notice of renewal of accreditation. One or more site evaluations will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the general requirements set forth in § 205.501.

§ 205.509 Peer review panel.

The Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 et seq.). The peer review panel shall be composed of not less than 3 members who shall annually evaluate the National Organic Program's adherence to the accreditation procedures in this subpart F and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the National Organic Program's accreditation decisions. This shall be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents or documentation. The peer review panel shall report its finding, in writing, to the National Organic Program's Program Manager.

§ 205.510 Annual report, recordkeeping, and renewal of accreditation.

(a) *Annual report and fees.* An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees:

(1) A complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504;

(2) Information supporting any changes being requested in the areas of accreditation described in § 205.500;

(3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation;

(4) The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and

(5) The fees required in § 205.640(a).

(b) *Recordkeeping.* Certifying agents must maintain records according to the following schedule:

(1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt;

(2) Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and

(3) Records created or received by the certifying agent pursuant to the accreditation requirements of this subpart F, excluding any records covered by §§ 205.510(b)(2), must be maintained for not less than 5 years beyond their creation or receipt.

(c) *Renewal of accreditation.* (1) The Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration.

(2) An accredited certifying agent's application for accreditation renewal must be received at least 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and the regulations of this part.

(3) Following receipt of the information submitted by the certifying agent in accordance with paragraph (a) of this section and the results of a site evaluation, the Administrator will determine whether the certifying agent remains in compliance with the Act and

the regulations of this part and should have its accreditation renewed.

(d) *Notice of renewal of accreditation.* Upon a determination that the certifying agent is in compliance with the Act and the regulations of this part, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied.

(e) *Noncompliance.* Upon a determination that the certifying agent is not in compliance with the Act and the regulations of this part, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation.

(f) *Amending accreditation.* Amendment to scope of an accreditation may be requested at any time. The application for amendment shall be sent to the Administrator and shall contain information applicable to the requested change in accreditation, a complete and accurate update of the information submitted pursuant to §§ 205.503 and 205.504, and the applicable fees required in § 205.640.

§§ 205.511–205.599 [Reserved]

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

§ 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes;

(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as

defined by applicable Federal regulations;

(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;

(5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and

(6) The substance is essential for the handling of organically produced agricultural products.

(c) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production:

(a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.

(1) Alcohols.

(i) Ethanol.

(ii) Isopropanol.

(2) Chlorine materials—*Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(3) Hydrogen peroxide.

(4) Soap-based algicide/demisters.

(b) As herbicides, weed barriers, as applicable.

(1) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.

(2) Mulches.

(i) Newspaper or other recycled paper, without glossy or colored inks.

(ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.

(d) As animal repellents—Soaps, ammonium—for use as a large animal repellent only, no contact with soil or edible portion of crop.

(e) As insecticides (including acaricides or mite control).

(1) Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.

(2) Boric acid—structural pest control, no direct contact with organic food or crops.

(3) Elemental sulfur.

(4) Lime sulfur—including calcium polysulfide.

(5) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.

(6) Soaps, insecticidal.

(7) Sticky traps/barriers.

(f) As insect attractants—Pheromones.

(g) As rodenticides.

(1) Sulfur dioxide—underground rodent control only (smoke bombs).

(2) Vitamin D₃.

(h) As slug or snail bait—None.

(i) As plant disease control.

(1) Coppers, fixed—copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, *Provided*, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.

(2) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.

(3) Hydrated lime—must be used in a manner that minimizes copper accumulation in the soil.

(4) Hydrogen peroxide.

(5) Lime sulfur.

(6) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.

(7) Potassium bicarbonate.

(8) Elemental sulfur.

(9) Streptomycin, for fire blight control in apples and pears only.

(10) Tetracycline (oxytetracycline calcium complex), for fire blight control only.

(j) As plant or soil amendments.

(1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.

(2) Elemental sulfur.

(3) Humic acids—naturally occurring deposits, water and alkali extracts only.

(4) Lignin sulfonate—chelating agent, dust suppressant, floatation agent.

(5) Magnesium sulfate—allowed with a documented soil deficiency.

(6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.

(i) Soluble boron products.

(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

(7) Liquid fish products—can be pH adjusted with sulfuric, citric or

phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.

(8) Vitamins, B₁, C, and E.

(k) As plant growth regulators—Ethylene—for regulation of pineapple flowering.

(l) As floating agents in postharvest handling.

(1) Lignin sulfonate.

(2) Sodium silicate—for tree fruit and fiber processing.

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern.

(n)–(z) [Reserved]

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

(a) Ash from manure burning.

(b) Arsenic.

(c) Lead salts.

(d) Sodium fluoaluminate (mined).

(e) Strychnine.

(f) Tobacco dust (nicotine sulfate).

(g) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.

(h) Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement.

(i)–(z) [Reserved]

§ 205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(1) Alcohols.

(i) Ethanol—disinfectant and sanitizer only, prohibited as a feed additive.

(ii) Isopropanol—disinfectant only.

(2) Aspirin—approved for health care use to reduce inflammation

(3) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(4) Chlorohexidine—Allowed for surgical procedures conducted by a

veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(5) Electrolytes—without antibiotics.

(6) Glucose.

(7) Glycerin—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(8) Iodine.

(9) Hydrogen peroxide.

(10) Magnesium sulfate.

(11) Oxytocin—use in postparturition therapeutic applications.

(12) Parasiticides—Ivermectin—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period of breeding stock.

(13) Phosphoric acid—allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.

(14) Biologics—Vaccines.

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(1) Iodine.

(2) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(3) Lime, hydrated—(bordeaux mixes), not permitted to cauterize physical alterations or deodorize animal wastes.

(4) Mineral oil—for topical use and as a lubricant.

(5) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(6) Copper sulfate.

(c) As feed supplements—Milk replacers without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals.

(d) As feed additives.

(1) Trace minerals, used for enrichment or fortification when FDA approved, including:

(i) Copper sulfate.

(ii) Magnesium sulfate.

(2) Vitamins, used for enrichment or fortification when FDA approved.

(e) As synthetic inert ingredients as classified by the Environmental

Protection Agency (EPA), for use with nonsynthetic substances or a synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(f) EPA List 4—Inerts of Minimal Concern.

(g)–(z) [Reserved]

§ 205.604 Nonsynthetic substances prohibited for use in organic livestock production.

The following nonsynthetic substances may not be used in organic livestock production:

(a) Strychnine.

(b)–(z) [Reserved]

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The following nonagricultural substances may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

(a) *Nonsynthetics allowed:*

(1) Acids.

(i) Alginic.

(ii) Citric—produced by microbial fermentation of carbohydrate substances.

(iii) Lactic.

(2) Bentonite.

(3) Calcium carbonate.

(4) Calcium chloride.

(5) Colors, nonsynthetic sources only.

(6) Dairy cultures.

(7) Diatomaceous earth—food filtering aid only.

(8) Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

(9) Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(10) Kaolin.

(11) Magnesium sulfate, nonsynthetic sources only.

(12) Nitrogen—oil-free grades.

(13) Oxygen—oil-free grades.

(14) Perlite—for use only as a filter aid in food processing.

(15) Potassium chloride.

(16) Potassium iodide.

(17) Sodium bicarbonate.

(18) Sodium carbonate.

(19) Waxes—nonsynthetic.

(i) Carnauba wax.

(ii) Wood resin.

(20) Yeast—nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited.

(i) Autolysate.

(ii) Bakers.
 (iii) Brewers.
 (iv) Nutritional.
 (v) Smoked—nonsynthetic smoke flavoring process must be documented.
 (b) *Synthetics allowed:*
 (1) Alginates.
 (2) Ammonium bicarbonate—for use only as a leavening agent.
 (3) Ammonium carbonate—for use only as a leavening agent.
 (4) Ascorbic acid.
 (5) Calcium citrate.
 (6) Calcium hydroxide.
 (7) Calcium phosphates (monobasic, dibasic, and tribasic).
 (8) Carbon dioxide.
 (9) Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
 (i) Calcium hypochlorite.
 (ii) Chlorine dioxide.
 (iii) Sodium hypochlorite.
 (10) Ethylene—allowed for postharvest ripening of tropical fruit.
 (11) Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).
 (12) Glycerides (mono and di)—for use only in drum drying of food.
 (13) Glycerin—produced by hydrolysis of fats and oils.
 (14) Hydrogen peroxide.
 (15) Lecithin—bleached.
 (16) Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
 (17) Magnesium chloride—derived from sea water.
 (18) Magnesium stearate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.
 (19) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.
 (20) Ozone.
 (21) Pectin (low-methoxy).
 (22) Phosphoric acid—cleaning of food-contact surfaces and equipment only.
 (23) Potassium acid tartrate.
 (24) Potassium tartrate made from tartaric acid.
 (25) Potassium carbonate.
 (26) Potassium citrate.
 (27) Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

(28) Potassium iodide—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

(29) Potassium phosphate—for use only in agricultural products labeled “made with organic (specific ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

(30) Silicon dioxide.

(31) Sodium citrate.

(32) Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

(33) Sodium phosphates—for use only in dairy foods.

(34) Sulfur dioxide—for use only in wine labeled “made with organic grapes,” *Provided*, That, total sulfite concentration does not exceed 100 ppm.

(35) Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.

(36) Xanthan gum.

(c)-(z) [Reserved]

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

Any nonorganically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form.

(a) Cornstarch (native)

(b) Gums—water extracted only (arabic, guar, locust bean, carob bean)

(c) Kelp—for use only as a thickener and dietary supplement

(d) Lecithin—unbleached

(e) Pectin (high-methoxy)

§ 205.607 Amending the National List.

(a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated by the Board for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with the Act.

(b) A person petitioning for amendment of the National List should request a copy of the petition procedures from the USDA at the address in § 205.607(c).

(c) A petition to amend the National List must be submitted to: Program

Manager, USDA/AMS/TMP/NOP, Room 2945, South Building, P.O. Box 96456, Washington, DC 20090-6456.

§§ 205.608–205.619 [Reserved]

State Organic Programs

§ 205.620 Requirements of State organic programs.

(a) A State may establish a State organic program for production and handling operations within the State which produce and handle organic agricultural products.

(b) A State organic program must meet the requirements for organic programs specified in the Act.

(c) A State organic program may contain more restrictive requirements because of environmental conditions or the necessity of specific production or handling practices particular to the State or region of the United States.

(d) A State organic program must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements approved by the Secretary.

(e) A State organic program and any amendments to such program must be approved by the Secretary prior to being implemented by the State.

§ 205.621 Submission and determination of proposed State organic programs and amendments to approved State organic programs.

(a) A State organic program’s governing State official must submit to the Secretary a proposed State organic program and any proposed amendments to such approved program.

(1) Such submission must contain supporting materials that include statutory authorities, program description, documentation of the environmental conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary.

(2) Submission of a request for amendment of an approved State organic program must contain supporting materials that include an explanation and documentation of the environmental conditions or specific production and handling practices particular to the State or region, which necessitates the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations of this part.

(b) Within 6 months of receipt of submission, the Secretary will: Notify the State organic program’s governing

State official of approval or disapproval of the proposed program or amendment of an approved program and, if disapproved, the reasons for the disapproval.

(c) After receipt of a notice of disapproval, the State organic program's governing State official may submit a revised State organic program or amendment of such a program at any time.

§ 205.622 Review of approved State organic programs.

The Secretary will review a State organic program not less than once during each 5-year period following the date of the initial program approval. The Secretary will notify the State organic program's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

§§ 205.623–205.639 [Reserved]

Fees

§ 205.640 Fees and other charges for accreditation.

Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions:

(a) *Fees-for-service.* (1) Except as otherwise provided in this section, fees-for-service shall be based on the time required to render the service provided calculated to the nearest 15-minute period, including the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the time required to prepare reports and any other documents in connection with the performance of service. The hourly rate shall be the same as that charged by the Agricultural Marketing Service, through its Quality Systems Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

(2) Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first

18 months following the effective date of subpart F of this part shall receive service without incurring an hourly charge for service.

(3) Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following February 20, 2001, a nonrefundable fee of \$500.00 which shall be applied to the applicant's fees-for-service account.

(b) *Travel charges.* When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such place and back to the headquarters or at a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service shall include a mileage charge administratively determined by the U.S. Department of Agriculture and travel tolls, if applicable, or such travel prorated among all the applicants and certifying agents furnished the service involved on an equitable basis or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. Travel charges shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

(c) *Per diem charges.* When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by the U.S. Department of Agriculture. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

(d) *Other costs.* When costs, other than costs specified in paragraphs (a), (b), and (c) of this section, are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include but are not limited to equipment rental, photocopying, delivery, facsimile, telephone, or

translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by the U.S. Department of Agriculture. Such costs shall become effective for all applicants for initial accreditation and accredited certifying agents on February 20, 2001.

§ 205.641 Payment of fees and other charges.

(a) Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee, pursuant to § 205.640(a)(3), along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, P.O. Box 96456, Washington, DC 20090-6456 or such other address as required by the Program Manager.

(b) Payments for fees and other charges not covered under paragraph (a) of this section must be:

(1) Received by the due date shown on the bill for collection;

(2) Made payable to the Agricultural Marketing Service, USDA; and

(3) Mailed to the address provided on the bill for collection.

(c) The Administrator shall assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

§ 205.642 Fees and other charges for certification.

Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring

about the application process with a copy of its fee schedule.

§§ 205.643–205.649 [Reserved]

Compliance

§ 205.660 General.

(a) The National Organic Program's Program Manager, on behalf of the Secretary, may inspect and review certified production and handling operations and accredited certifying agents for compliance with the Act or regulations in this part.

(b) The Program Manager may initiate suspension or revocation proceedings against a certified operation:

(1) When the Program Manager has reason to believe that a certified operation has violated or is not in compliance with the Act or regulations in this part; or

(2) When a certifying agent or a State organic program's governing State official fails to take appropriate action to enforce the Act or regulations in this part.

(c) The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain accreditation requirements pursuant to the Act or this part.

(d) Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to § 205.662, § 205.663, and § 205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.

§ 205.661 Investigation of certified operations.

(a) A certifying agent may investigate complaints of noncompliance with the Act or regulations of this part concerning production and handling operations certified as organic by the certifying agent. A certifying agent must notify the Program Manager of all compliance proceedings and actions taken pursuant to this part.

(b) A State organic program's governing State official may investigate complaints of noncompliance with the Act or regulations in this part concerning organic production or handling operations operating in the State.

§ 205.662 Noncompliance procedure for certified operations.

(a) *Notification.* When an inspection, review, or investigation of a certified operation by a certifying agent or a State

organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) *Resolution.* When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution.

(c) *Proposed suspension or revocation.* When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state:

(1) The reasons for the proposed suspension or revocation;

(2) The proposed effective date of such suspension or revocation;

(3) The impact of a suspension or revocation on future eligibility for certification; and

(4) The right to request mediation pursuant to § 205.663 or to file an appeal pursuant to § 205.681.

(d) *Willful violations.*

Notwithstanding paragraph (a) of this section, if a certifying agent or State organic program's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.

(e) *Suspension or revocation.* (1) If the certified operation fails to correct the

noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation.

(2) A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to § 205.663 or filed an appeal pursuant to § 205.681, while final resolution of either is pending.

(f) *Eligibility.* (1) A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, *Except*, That, the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

(g) *Violations of Act.* In addition to suspension or revocation, any certified operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 per violation.

(2) Makes a false statement under the Act to the Secretary, a State organic program's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

§ 205.663 Mediation.

Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent. If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. The written notification shall advise the

applicant for certification or certified operation of the right to request an appeal, pursuant to § 205.681, within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to § 205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and the regulations in this part. The Secretary may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.

§ 205.664 [Reserved]

§ 205.665 Noncompliance procedure for certifying agents.

(a) *Notification.* When an inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certifying agent. Such notification shall provide:

- (1) A description of each noncompliance;
- (2) The facts upon which the notification of noncompliance is based; and
- (3) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.

(b) *Resolution.* When the certifying agent demonstrates that each noncompliance has been resolved, the Program Manager shall send the certifying agent a written notification of noncompliance resolution.

(c) *Proposed suspension or revocation.* When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the

certifying agent. The notification of proposed suspension or revocation shall state whether the certifying agent's accreditation or specified areas of accreditation are to be suspended or revoked. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation may be combined in one notification. The notification of proposed suspension or revocation of accreditation shall state:

- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of the suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for accreditation; and
- (4) The right to file an appeal pursuant to § 205.681.

(d) *Willful violations.* Notwithstanding paragraph (a) of this section, if the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations in this part, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent.

(e) *Suspension or revocation.* When the accredited certifying agent fails to file an appeal of the proposed suspension or revocation of accreditation, the Program Manager shall send a written notice of suspension or revocation of accreditation to the certifying agent.

(f) *Cessation of certification activities.* A certifying agent whose accreditation is suspended or revoked must:

- (1) Cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked.
- (2) Transfer to the Secretary and make available to any applicable State organic program's governing State official all records concerning its certification activities that were suspended or revoked.

(g) *Eligibility.* (1) A certifying agent whose accreditation is suspended by the Secretary under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certifying agent whose accreditation is revoked by the Secretary shall be ineligible to be accredited as a certifying agent under the Act and the

regulations in this part for a period of not less than 3 years following the date of such revocation.

§§ 205.666–205.667 [Reserved]

§ 205.668 Noncompliance procedures under State organic programs.

(a) A State organic program's governing State official must promptly notify the Secretary of commencement of any noncompliance proceeding against a certified operation and forward to the Secretary a copy of each notice issued.

(b) A noncompliance proceeding, brought by a State organic program's governing State official against a certified operation, shall be appealable pursuant to the appeal procedures of the State organic program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located.

(c) A State organic program's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the State organic program's governing State official shall send a written report of noncompliance to the Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based.

§ 205.669 [Reserved]

Inspection and Testing, Reporting, and Exclusion from Sale

§ 205.670 Inspection and testing of agricultural product to be sold or labeled "organic."

(a) All agricultural products that are to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying agent.

(b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come

into contact with a prohibited substance or has been produced using excluded methods. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) The preharvest or postharvest tissue test sample collection pursuant to paragraph (b) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the *Official Methods of Analysis of the AOAC International* or other current applicable validated methodology determining the presence of contaminants in agricultural products.

(d) Results of all analyses and tests performed under this section:

(1) Must be promptly provided to the Administrator; *Except*, That, where a State organic program exists, all test results and analyses shall be provided to the State organic program's governing State official by the applicable certifying party that requested testing; and

(2) Will be available for public access, unless the testing is part of an ongoing compliance investigation.

(e) If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency whose regulatory tolerance or action level has been exceeded.

§ 205.671 Exclusion from organic sale.

When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced. The Administrator, the applicable State organic program's governing State official, or the certifying agent may conduct an investigation of the certified operation to determine the cause of the prohibited substance.

§ 205.672 Emergency pest or disease treatment.

When a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited substance: *Provided*, That:

(a) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as organically produced; and

(b) Any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as organically produced: *Except*, That:

(1) Milk or milk products may be sold, labeled, or represented as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance; and

(2) The offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic: *Provided*, That, the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

§§ 205.673–205.679 [Reserved]

Adverse Action Appeal Process

§ 205.680 General.

(a) Persons subject to the Act who believe they are adversely affected by a noncompliance decision of the National Organic Program's Program Manager may appeal such decision to the Administrator.

(b) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a State organic program may appeal such decision to the State organic program's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.

(c) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator, *Except*, That, when the person is subject to an approved State organic program, the

appeal must be made to the State organic program.

(d) All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts.

(e) All appeals shall be reviewed, heard, and decided by persons not involved with the decision being appealed.

§ 205.681 Appeals.

(a) *Certification appeals.* An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the Administrator, *Except*, That, when the applicant or certified operation is subject to an approved State organic program the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.

(1) If the Administrator or State organic program sustains a certification applicant's or certified operation's appeal of a certifying agent's decision, the applicant will be issued organic certification, or a certified operation will continue its certification, as applicable to the operation. The act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent.

(2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice or the State organic program's rules of procedure.

(b) *Accreditation appeals.* An applicant for accreditation and an accredited certifying agent may appeal the Program Manager's denial of accreditation or proposed suspension or revocation of accreditation to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding to deny, suspend, or revoke the accreditation will be initiated. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, Subpart H.

(c) *Filing period.* An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. A decision to deny, suspend, or revoke certification or accreditation will become final and nonappealable unless the decision is appealed in a timely manner.

(d) *Where and what to file.* (1) Appeals to the Administrator must be filed in writing and addressed to Administrator, USDA-AMS, Room 3071-S, P.O. Box 96456, Washington, DC 20090-6456.

(2) Appeals to the State organic program must be filed in writing to the address and person identified in the letter of notification.

(3) All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

§§ 205.682–205.689 [Reserved]

Miscellaneous

§ 205.690 OMB control number.

The control number assigned to the information collection requirements in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, is OMB number 0581-0181.

§§ 205.691–205.699 [Reserved]

PARTS 206–209 [Reserved]

Dated: December 13, 2000.

Kathleen A. Merrigan,
Administrator, Agricultural Marketing Service.

Appendixes to Preamble

Appendix A—Regulatory Impact Assessment for Final Rule Implementing the Organic Foods Production Act of 1990

The following regulatory assessment is provided to fulfill the requirements of Executive Order 12866. This assessment consists of a statement of the need for national organic standards, a description of the baseline for the analysis, a summary of the provisions of the final U.S. Department of Agriculture (USDA) rule and the alternative approaches that were examined, and an analysis of the benefits and costs. Much of the analysis is necessarily descriptive of the anticipated effects of the final rule. Because basic market data on the prices and quantities of organic goods and the costs of organic production are limited,

it is not possible to provide quantitative estimates of all benefits and costs of the final rule. The cost of fees and recordkeeping in the final USDA rule are quantified, but the anticipated benefits and other costs are not. Consequently, the analysis does not estimate the magnitude or the direction (positive or negative) of net benefits.

Under the final rule, USDA will implement a program of uniform standards of production and certification, as mandated by the Organic Foods Production Act of 1990 (OFPA). The primary benefits from implementation of USDA's National Organic Program (NOP) are standardizing the definitions and the manner in which organic product information is presented to consumers, which may reduce the cost associated with enforcement actions in consumer fraud cases, and improved access to domestic and international markets from harmonizing the various State and private organic standards and elevating reciprocity negotiations to the national level.

The costs of this rule are the direct costs for accreditation and the costs of complying with the specific standards in the proposal, including the reporting and recordkeeping requirements. Certifiers will be charged fees based on the actual costs of the accreditation work done by USDA staff. Smaller certifiers with less complex programs are expected to pay somewhat lower fees. Organic farmers, ranchers, wild-crop harvesters, and handlers will have to pay fees for organic certification from a State or private certifier but will not be charged any additional fees by USDA. The direct accreditation costs to an estimated 59 certifying agents (including all 49 current U.S. certifiers and an estimated 10 foreign agents) during the first 18 months following the final rule are estimated to be approximately \$92,000 to \$124,000 and are being subsidized with appropriated funds derived from the taxpayers. In addition, USDA will use appropriated funds to cover approximately \$270,000–\$448,000 in hourly charges for site evaluation during this period and for other costs associated with starting up the NOP. The magnitude of other compliance costs for adhering to this regulation—including the costs of becoming familiar with and adopting the national standards—have not been measured. For organic farmers who adhere to State regulations or undergo third-party inspection and certification, the compliance cost may not be large. For those who don't, the costs may be more substantial. The impact of this regulation on small certifying agents and other small businesses has also not been measured but may be significant.

To account for significant rule changes from the proposal and to reflect more up-to-date information, we revised some estimates of benefits and costs. We have raised our estimates of current certification fees and USDA accreditation fees. Also, we now project higher USDA accreditation fees after the 18-month implementation period. We revised our estimates of the certification fees charged by a representative set of public and private certifiers in the U.S. based on new data, and our new estimates are about 25 percent higher for small and midsized farmers. Small and midsized farmers are now

estimated to pay \$579 and \$1,414 for their first-year certification, respectively. Accreditation costs after the 18-month implementation period are substantially above those estimated in the proposed rule, reflecting a slight increase in the government per diem travel allowance since the proposed rule was published and a change in the projected number of reviewers needed for site evaluations and renewals after the 18-month implementation period. In the proposed rule, USDA had projected that only one reviewer would be needed for site evaluations and renewals that took place after the 18-month implementation period but has changed that projection to two reviewers based on additional experience with the International Organization for Standardization (ISO Guide 65) program. We estimate that initial accreditation costs after the 18-month implementation period will range from \$6,120 to \$9,700, approximately double our estimate in the March 2000 proposed rule.

Marginal changes have been made in the final rule, in response to comments on the March 2000 proposal, which generally clarify or add flexibility to producer and handler provisions or make them better reflect current industry standards. One key change was to raise the threshold for labeling products as "made with organic ingredients" from 50 percent organic content to 70 percent to be consistent with international industry standards. Although not quantified, we believe that this will increase the cost of the rule. Another key change was to reduce the transition period for a dairy operation to make a whole-herd conversion to organic production in order to make conversion affordable for a wider range of dairy farms, including smaller operations. Although not quantified, we believe that this will decrease the cost of the rule.

The Need for National Standards

Over the last several decades, as market demand has grown from a handful of consumers bargaining directly with farmers to millions of consumers acquiring goods from supermarket shelves as well as market stalls, a patchwork of State and private institutions has evolved to set standards and verify label claims. Organically produced food cannot be distinguished visually from conventional food and cannot necessarily be distinguished by taste; therefore, consumers must rely on labels and other advertising tools for product information. Farmers, food handlers, and other businesses that produce and handle organically grown food have a financial incentive to advertise that information because consumers have been willing to pay a price premium for these goods. However, consumers face difficulties in discerning the organic attributes of a product, and many producers and handlers have sought third-party certification of organic claims.

State and private initiatives have resulted in a fairly robust system of standards and certification, and the difficulties in consumer verification have been partially overcome by these initiatives. Private organizations, mostly nonprofits, began developing certification standards in the early 1970's as

a way to support organic farming, as well as to strengthen legitimate product claims. The first organization to offer third-party certification, California Certified Organic Farmers, was formed in the early 1970's, and the first State regulations and laws on organic labeling were also passed in the 1970's. Currently, 13 State and 36 private certification programs are operating in the United States, and about half the States currently have some form of regulation. While most States still do not mandate third-party certification and many organic producers still market goods without certification, large food processors, grain traders, and retailers are increasingly requiring certification, and many growers have turned to certification as a marketing tool.

However, even with increasing pressure for growers to use third-party certification services and increasing availability of these services from State and private certifiers, the discrepancies between the certifiers on organic standards and between the States on certification requirements have resulted in several impediments to market development. The patchwork of variable standards has made producer access to organic markets, international and domestic, uneven. The recent emergence of the industry-developed standards may have mitigated some domestic access problems, but two important impediments remain. They are: multiingredient certification disputes and barriers to foreign markets.

Difficulty Certifying Multiingredient Products

Although the State and private organic standards that have developed over the last several decades have many areas of overlap, particularly for crop production, the differences have caused disagreements among certifying agents over whose standards apply to multiingredient organic processed products. These disagreements have created sourcing problems for food. Disagreements about standards also create sourcing problems for handlers of these multiingredient products. Certifying agents are able to negotiate and maintain reciprocity agreements at some cost. These reciprocity agreements specify the conditions under which certifying agents recognize each other's standards. Although new organic product offerings have emerged at a fast pace during the 1990's, this pace could eventually slow, assuming that the need for costly reciprocity agreements will continue to persist in the absence of national standards.

Barriers to Foreign Organic Markets

In the absence of a national standard, U.S. producers have taken on costs of private accreditation or shipment-by-shipment certification required to gain access to some foreign markets such as the European Union (EU). However, even with these actions, U.S. organic products may have had some difficulties entering other foreign markets due to high information and search costs on the part of foreign buyers. Some foreign buyers of U.S. organic products may incur costs to determine the compatibility of standards. Such costs may have discouraged purchases of U.S. organic products.

Congress passed the OFPA—Title XXI of the Food, Agriculture, Conservation and Trade Act of 1990, U.S.C. Title 7—largely to address these marketing problems. The OFPA mandates that the Secretary of Agriculture develop a national organic program, and USDA's statutory responsibility is the primary reason why USDA has carried out this rulemaking process. The OFPA requires the Secretary to establish an organic certification program for farmers, wild-crop harvesters, and handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. This legislation requires the Secretary to establish and implement a program to accredit a State program official or any private person who meets the requirements of the Act as a certifying agent to certify that farm, wild-crop harvesting, or handling operations are in compliance with the standards set out in the regulation. As stated by the OFPA in section 6501, the regulations are for the following purposes: (1) To establish national standards governing the marketing of certain agricultural products as organically produced products, (2) to assure consumers that organically produced products meet a consistent standard, and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

Baseline

After struggling to build market recognition and supply capacity for many decades, the organic farming industry became one of the fastest growing segments of U.S. agriculture during the last decade. Certified organic cropland more than doubled in the United States between 1992 and 1997, and two organic livestock sectors—eggs and dairy—grew even faster (Greene, 2000a). USDA's Economic Research Service estimates that over 1.3 million acres of U.S. farmland were certified in 1997, and more recent data from some of the certifiers indicate that this momentum is continuing (Greene, 2000b). Although national estimates of the amount of uncertified organic acreage are not available, data from California, the largest U.S. producer of organic specialty crops, indicates that most of the State's organic acreage and about half of the growers were certified during the 1997/98 crop year (Klonsky et al., 2000).

Growth in U.S. sales of organic products during the 1990's mirrors the growth in acreage devoted to producing these goods. According to industry data, total organic product sales more than doubled between 1992 and 1996 to \$3.5 billion in sales (table 1). More recent industry data on organic sales through natural product stores, the largest outlet for organic products, show annual sales growth continuing in the general range of 20–25 percent annually.

The recent growth in organic production and sales has taken place in the absence of national organic standards but with industry expectation that these standards were forthcoming. While the U.S. organic industry is characterized by an array of certification, production, processing, and marketing practices, there are commonalities throughout the industry.

Certification

The number of U.S. certification groups has fluctuated between 40 and 50 during the last decade. Currently, 49 organizations—36 private and 13 State—are advertising that they provide certification services to farmers, handlers (a category that USDA defines to include processors), retailers, or other segments of the food industry. Some certifiers provide services to multiple segments of the food industry. Private certifying agents range from small nonprofit associations that certify only a few growers to large for-profit businesses operating in numerous States and certifying hundreds of producers. Typically, certifying agents review organic production plans, inspect the farm fields and facilities to be certified, periodically reinspect, and may conduct soil tests and tests for residues of prohibited substances. In some cases, certifying agents negotiate reciprocity agreements with other agents.

State laws vary widely on organic certification and registration. Some States, such as California, require only that an organic producer register and make certification voluntary. Other States, including Texas, require certification by the State's own agents, while Minnesota and others accept certification by a private certifying agent. Approximately half of the States have laws that regulate organic production and processing. In many States producers may claim their product is organic but operate without certification or well-defined standards. Many organic producers in States with no State programs voluntarily secure third-party certification to well-defined standards. Certification costs vary with farm size and across certifying agents. Illustrative certification costs are presented in tables 2A and 2B.

Very few certifying agents operate with an external accreditation for the following reasons. There is no law which requires them to be accredited: the price may be unacceptably high in relation to expected benefits; the certifying agent may be unable to find an accrediting party willing to accredit the particular organic program the certifying agent is marketing; and State programs may believe that their status as a government entity obviates the need for external accreditation.

In 1999, USDA began accrediting certifying agents as meeting ISO Guide 65. It is a valuable recognition that the certifying entity satisfies the business capacity standards of ISO Guide 65. EU authorities have accepted verification of certifying agents to ISO Guide 65 as an interim measure to facilitate exports pending the establishment of a national organic program.

Organic Crop and Livestock Production

In 1997, farmers in 49 States used organic production systems and third-party organic certification services on over a million acres of farmland and were raising certified organic livestock production in nearly half the States, according to USDA data (Greene, 2000a). Two-thirds of the farmland was used for growing crops, with Idaho, California, North Dakota, Montana, Minnesota, Wisconsin, Iowa, and Florida as the top producers.

Colorado and Alaska had the most organic pasture and rangeland. California overwhelmingly had the most certified organic fruit and vegetable acreage in 1997, but farmers were growing small plots of certified organic vegetables for direct marketing to consumers in over half the States. About 2 percent of the U.S. apple, grape, lettuce, and carrot crops were certified organic in 1997, while only one-tenth of 1 percent of the U.S. corn and soybean crops were grown under certified organic farming systems. USDA has not estimated the amount of acreage devoted to organic production systems that has not been certified, although data from California suggest that a large number of farmers, mostly those with small operations, produce and market organic goods without third-party certification.

Key production practices followed by certified organic producers include: abstaining from use of certain crop chemicals and animal drugs; ecologically based pest and nutrient management; segregation of organic fields and animals from nonorganic fields and animals; following an organic system plan with multiple goals, including sustainability; and recordkeeping to document practices and progress toward the plan's goals. Specific elements of organic production vary, but organic systems generally share a core set of practices. For example, the certification standards of virtually all State and private U.S. certifying agents prohibit the use of synthetic chemical pesticides or animal growth hormones. And most certification standards include a 3-year ban on the use of prohibited substances on cropland before production can be certified as organic.

On the other hand, certification standards for organic livestock production have been more variable for pasture, feed, and other practices. Until 1999, the USDA Food Safety and Inspection Service (FSIS) withheld approval for the use of organic labels on meat and poultry products pending the outcome of this rulemaking. However, the Secretary announced a change in policy in January 1999. Meat and poultry products may be labeled "certified organic by (name of the certifying agent)" if handlers obtain prior label approval from FSIS and the claim meets certain basic criteria. Organic labels have been permitted on eggs and dairy products—which are regulated by the Food and Drug Administration (FDA)—throughout the 1990's, but most certifiers have not yet offered certification services for these products.

We provide a summary of the New Hampshire organic program to highlight the similarities in the core set of practices. It is important to note that this discussion is intended to highlight the conceptual similarities between State and private programs and is not intended to suggest that these programs are identical to each other or to the NOP. Production standards include: a written rotation plan; tillage systems that incorporate organic matter wastes into the topsoil; compliance with limits on the sources of manure and the timing of its application; prohibitions on the use of certain substances (e.g., sewage sludge, synthetic sources of nitrates, synthetic

growth regulators, and anhydrous ammonia); a list of accepted and prohibited weed and pest control practices; segregation of organic and nonorganic production; recordkeeping regarding fertilization, cropping, and pest management histories; separate sales records for organic and nonorganic production; and records of all laboratory analyses. Residue testing may be required if USDA believes that the products or soil used for producing certified products may have become contaminated with prohibited substances.

The New Hampshire program requires growers to pay a \$100 annual inspection fee and to provide a written description of their farm operation, including the size of the farm; a field map; a 3-year history of crop production, pest control, and fertilizer use; a crop rotation and a soil management plan; and a description of postharvest storage and handling methods. Applicants for certification must also agree to comply with regulations controlling the use of the New Hampshire certified organic logo.

Organic Food Handling

In addition to growers, who actually produce and harvest products to be marketed as organic, there are handlers who transform and resell the organic products. Not all certifiers have standards for handling organic products. And some certifiers have standards for parts of the food marketing system, such as restaurants, which are not explicitly covered by the OFPA nor encompassed by this final regulation.

Definitions of processing and handling differ across certifying agents and State laws. Some States, such as Washington, distinguish between a processor and a handler, specifying 21 actions which constitute processing and defining a handler as anyone who sells, distributes, or packs organic products. Other States do not distinguish between food processors and handlers. Under the final rule, the term, "handler," includes processors but not final retailers of agricultural products that do not process agricultural products.

Organic Product Marketing

The two largest marketing outlets for organically produced goods are natural foods stores and direct markets—which include farmers markets, roadside stands, and 'community supported agriculture' arrangements—according to industry data. USDA does not have official national level statistics on organic retail sales, but an industry trade publication, the Natural Foods Merchandiser (NFM), reported estimates of total retail sales of organic foods for years 1990–96 and continues to report estimates of natural product stores sales (table 1). The last NFM estimate of total organic sales through all marketing outlets was \$3.5 billion in 1996 (\$3.7 billion in 1999 dollars), less than one percent of total food expenditures by families and individuals that year.

Natural foods stores increased in size and presence in the United States during the 1990's—many are now the size of conventional supermarkets—and about two-thirds of estimated total organic sales during the 1990's were through this outlet (table 1). Natural foods supermarkets, which are

similar to conventional in the breadth of supermarket offerings and amount of total sales, accounted for close to 1 percent of total supermarket sales by 1997 (Kaufman 1998). Organic product sales through the natural foods stores outlet, alone, in 1999 were estimated at \$4 billion, and sales through this outlet increased about 20–25 percent annually through the 1990's.

Direct-to-consumer market sales ranged from \$270 to \$390 million during the early 1990's, accounting for between 17 and 22 percent of total organic sales during this period, according to NFM estimates (table 1). Conventional food stores (mass markets) accounted for 6–7 percent of total sales during this period, and export sales accounted for 3–8 percent of the total. A draft report on the U.S. organic export market, partly funded by USDA, indicates that current U.S. export sales are under 5 percent of total organic product sales (Fuchshofen and Fuchshofen 2000).

The United States is both an importer and an exporter of organic foods. The United States does not restrict imports of organic foods. In fact, U.S. Customs accounts do not distinguish between organic and conventional products. The largest markets for organic foods outside the United States are in Europe, Japan, and Canada. There is increasing pressure, particularly in Europe and Japan, for U.S. exports to demonstrate that they meet a national standard rather than a variety of private and State standards. France, for example, has indicated to USDA that it prefers to negotiate with a single national organic program, rather than the dozens of different State and private certifying programs currently operating in the U.S.

The EU is the largest market for organic food outside the United States. The organic food market in the EU was estimated to be worth \$5.2 billion in 1997 (International Trade Centre UNCTAD/WTO 1999). The largest organic retail sales markets in the EU in 1997 were Germany (\$1.8 billion), France (\$720 million), and Italy (\$750 million). Large organic markets outside the EU include Canada and Australia, with approximately \$60 million and \$68 million, respectively, in organic retail sales in 1997 (Lohr 1998). Import share of the organic food market in Europe ranged from 10 percent in France to 70 percent in the United Kingdom, was 80 percent in Canada, and varied from 0 to 13 percent in various Australian States.

Japan is another important market for U.S. organic products. Currently, Japan has voluntary labeling guidelines for 6 categories of nonconventional agricultural products: organic, transitional organic, no pesticide, reduced pesticide, no chemical fertilizer, and reduced chemical fertilizer. Total sales, including foods marketed as "no chemical" and "reduced chemical," are forecast to jump 15 percent in 1999 to almost \$3 billion. Imports of organic agricultural products were valued at \$90 million in 1998. Given Japan's limited agricultural acreage, imports will likely provide an increasingly significant share of Japan's organic food supply (USDA FAS 1999a).

Recently, these markets have adopted or are considering adoption of procedures that

may impede the importing of organic food. The EU regulations establishing the basis for equivalency in organic production among EU members and for imports from outside the EU were adopted in 1991 (Council Regulation 2092/91). The EU regulations only allow imports from non-EU countries whose national standards have been recognized as equivalent to the EU standards (Commission Regulation 94/92).

The Ministry of Agriculture, Forestry, and Fisheries (MAFF) in Japan recently announced proposed standards and third-party certification requirements. Under Japan's proposed standards, certifying agents from countries without national organic standards administered by a federal government will face additional financial and administrative costs.

Requirements of the Final Rule

The final rule follows the structure established in the OFPA. By adopting this alternative, the Department is following the legislative direction in the OFPA. All products marketed as organic will have to be produced and handled as provided in the OFPA and these regulations. Compared to current organic practices, the final rule sets a somewhat more stringent system of requirements.

Among many alternatives, two alternatives to the final rule are discussed in this section: continuation of the status quo and use of industry-developed standards. Given the statutory responsibility, USDA is implementing the requirements of the OFPA. However, under the status quo alternative, there would be no national standard or national program of accreditation and certification. No Federal funds would be used, there would be no transfer from Federal taxpayers at large to organic market participants, and there would be no Federal regulatory barriers to entry into organic production and handling. However, growers and handlers would still not have level access, under uniform standards, to the domestic market, and there may be significant enforcement gaps at the State level. International pressure for additional verification would continue to build and would be likely to lead to an increased use of public and private verification and accreditation services, which are provided on a user-fee basis with full cost recovery. Establishing reciprocity between certifying agents in the domestic organic market would continue to be costly and may stifle growth in trade of organic products, although the magnitude of these costs and their effects on growth are unknown. Without further analysis that includes quantification and monetization of benefits and costs, it is not clear whether the net benefits associated with this alternative are greater or less than those associated with the final rule.

Under the other industry-developed standards alternative, USDA could eliminate the costs associated with establishing reciprocity in the domestic market and establish equivalency for access to international markets, but it would be difficult for industry to develop consensus standards. For example, the industry-developed standards recently proposed by

the Organic Trade Association were developed with significant industry input but with little public comment. In contrast, several hundred thousand comments have been submitted in the course of the USDA rulemaking process. In addition, the OFPA mandated an advisory role for a 15-member National Organic Standards Board (NOSB), which has wide representation from the organic community and includes members who are farmers, handlers, retailers, environmentalists, consumers, scientists, and certifiers. The NOSB has assisted in developing the standards promulgated in this final rule and will play an advisory role for the NOP even after the final rule is in place. Without further analysis that includes quantification and monetization of benefits and costs, it is not clear whether the net benefits associated with this alternative are greater or less than those associated with the final rule.

USDA's final rule will be implemented by the NOP staff in the Agricultural Marketing Service (AMS). Major features of the NOP include:

Accreditation and Certification

The rule specifies the accreditation and certification process. Persons providing certification services for organic production and handling must be accredited by USDA through the NOP. Applicants for accreditation must document their abilities to certify according to the national standards and to oversee their client's compliance with the requirements of the OFPA and NOP regulations. Producers and handlers of organic products must be certified by an accredited certifying agent. Producers and handlers are required to document their organic plans and procedures to ensure compliance with the OFPA.

All certifying agents would have to be accredited, and certification by producers and handlers would be mandatory. The exceptions are: (1) growers and handlers with gross organic sales of \$5,000 or less would be exempt from certification, and (2) a handling operation may be exempt or excluded from certification according to provisions described in the rule's subpart B, *Applicability*.

USDA will charge applicants for accreditation and accreditation renewal (required every 5 years) a \$500 fee at the time of application. USDA will also charge applicants for costs over \$500 for site evaluation of the applicant's business. The applicant would be charged for travel costs, per diem expenses, and any miscellaneous costs incurred with a site evaluation. USDA will also charge accredited certifiers at an hourly rate to review their annual reports.

Producers and handlers will not pay certification fees to USDA. Certification fees will be established by the accredited certifying agents. USDA will not set fees. The rule requires certifying agents to submit a copy of their fee schedules to USDA, post their fees, and provide applicants estimates of the costs for initial certification and for renewal of certification.

Production and Handling

The rule establishes standards for organic production of crops and livestock and

handling of organic products. These standards were developed from specific requirements in the OFPA, recommendations from the NOSB, review of existing organic industry practices and standards, public comments received on the 1997 proposal and subsequent issue papers, public meetings, and comments received on the 2000 proposal.

The final rule establishes a number of requirements for producers and handlers of organic food. These requirements will affect farming operations, packaging operations, processing operations and retailers. Some of the major provisions are: (1) land requirements, (2) crop nutrient requirements, (3) crop rotation requirements, (4) pest management requirements, (5) livestock management requirements, (6) processing and handling requirements, and (7) commingling requirements.

National List

The National List lists allowed synthetic substances and prohibited nonsynthetic substances that may or may not be used in organic production and handling operations. The list identifies those synthetic substances, which would otherwise be prohibited, that may be used in organic production based on the recommendations of the NOSB. Only those synthetic substances on the National List may be used. The National List also identifies those natural substances that may not be used in organic production, as determined by the Secretary based on the NOSB recommendations.

Testing

When certifying agents have reason to believe organic products contain a prohibited substance, they may conduct residue tests.

Labeling

The rule also states how organic products may be labeled and permitted uses of the USDA organic seal. In addition to the USDA seal and the certifying agent's seal, information on organic food content may be displayed. Small businesses that are certified may use the USDA seal.

Recordkeeping

The rule requires certifying agents, producers, and handlers to keep certain records. Certifying agents are required to file periodic reports with USDA. Producers and handlers are required to notify and submit reports to their certifying agent. While recordkeeping is a standard practice in conventional and organic farming, the final rule adds recordkeeping and reporting requirements that do not exist for growers and handlers operating without certification. Similarly, certifying agents would face additional recordkeeping and reporting requirements, particularly those certifying agents operating without external accreditation. The rule permits certifying agent logos and requires the name of the certifying agent on processed organic foods.

Enforcement

Organic operations that falsely sell or label a product as organic will be subject to civil penalties of up to \$10,000 per violation. The provisions of the final regulation apply to all

persons who sell, label, or represent their agricultural product as organic, including operations that aren't certified, and the civil penalties of up to \$10,000 apply to these operations as well. Certifying agents, State organic programs' governing State officials, and USDA will receive complaints alleging violations of the Act or these regulations. In States where there is no State organic program, USDA will investigate allegations of violations of the Act.

Number of Affected Parties and Projections

In assessing the impacts of the rule, we have attempted to determine the number of certifying agents, private and State, that are currently operating and considered the factors likely to affect the number of certifying agents after the rule is implemented. We have attempted to determine the number of currently operating producers and handlers that would be affected. And, we have considered the factors that might affect the number of producers and handlers after the program has been implemented.

For the analysis, USDA assumes the following:

1. Forty-nine domestic certifying agents and ten foreign certifying agents will be affected by the regulation.

2. Approximately 13,650 certified and noncertified organic producers will be affected by the regulation. With the assumed growth rate of 14 percent for certified organic producers and approximately 8 percent for noncertified organic producers, the number of organic producers will grow to 17,150 in 2002.

3. Approximately 1,600 handlers of organic food will be affected by the regulation. This number will grow to 2,250 by 2002.

Certifying Entities

We place the number of certifying agents currently operating at 49, including 13 State programs. The number of certifying agents has remained fairly stable, between 40 and 50, for some years, with entries and exits tending to offset each other. For purposes of estimating the paperwork burden described elsewhere, we assume no growth in the number of domestic certifying agents but project 10 foreign certifying agents will seek and receive USDA accreditation in the first 3 years of the program.

Organic Producers

While some USDA data on the number of certified organic producers in the United States exist, no national data have been collected on the number of producers that produce and market organic goods without third-party certification. Organic farming was not distinguished from conventional agriculture in the last Census of Agriculture in 1997. USDA and Organic Farming Research Foundation (OFRF) data were used in the Regulatory Impact Analysis (RIA) of the March 2000 proposed rule to help estimate the number of certified U.S. growers affected by the regulation. California Department of Food and Agriculture (CDFA) data were used to help estimate the number of uncertified U.S. growers affected by the regulation. All three of these data sources have updated their estimates of the number

of certified and uncertified organic producers since the RIA of the proposed rule was published earlier this year. However, the updated numbers do not indicate trends that would fundamentally alter the assumptions used in the RIA of the proposed rule to calculate the number of affected growers, and the estimates made for the March 2000 RIA are retained in this assessment of the final rule.

USDA datum indicates the average annual growth rate in the number of U.S. certified organic growers between 1991 and 1994 was about 14 percent (Dunn 1995b). In April 2000, USDA's Economic Research Service estimated that 5,021 certified organic growers operated 1.347 million acres of U.S. farmland in 1997, indicating that the increase in acreage had outpaced the increase in growers, and showing only an 8 percent annual growth rate in growers between 1994 and 1997 (Greene, 2000b). However, USDA's study indicated that the pace of growth in certified acreage had quickened considerably since 1997, with the amount of certified acreage increasing 38 to 150 percent between 1997 and 1999 by several large certifying organizations across the U.S. And a nonprofit organic research foundation, OFRF, estimates that the number of certified organic producers in the certification organizations that they track—the ones that will release data to them—grew over 20 percent annually between 1997 and 1999, from 4,638 to 6,600 (OFRF 2000). Also, one certifier, Washington State, responded to our request for data on the growth rate, indicating that the number of certified organic producers has increased an average of 17 percent per year between 1994 and 1999 in that State and noting that certification became mandatory by State law in 1993.

In the March 2000 RIA, USDA estimated that the number of certified U.S. organic producers potentially affected by this legislation is approximately 9,350 in 2000 and will be approximately 12,150 in 2002, based on a straight line projection of the 14-percent annual growth rate trend shown by USDA data for 1991–1994. The period, 2000–2002, was chosen for analysis because it encompasses both the period of final rulemaking and the 18-month implementation period. Congress passed the OFPA in 1990, and the 14-percent growth rate in certified growers during the 1991–1994 period reflects their expectation that national organic regulations were forthcoming. Since the recent estimates of industry growth during the 1990's are uneven and the actual growth rate in the number of growers who will become certified after this legislation is implemented is uncertain, the March 2000 estimates are retained in this assessment of the final rule.

The March 2000 RIA also estimated the number of producers who are practicing organic agriculture but who are currently uncertified that would be affected by the rule. In California, where organic growers are required to register with the State but not to be certified, a large proportion of growers are uncertified. The most recent State data, for the 1997/98 crop year, indicate that 1,526 growers registered as organic, but only 41 percent of them obtained third-party

certification (Klonsky et al., 2000). While only a small percentage of growers in the lowest organic sales category (0–\$10,000), where the largest number of growers were clustered, obtained certification, three-quarters or more of the growers earning at least \$50,000 obtained certification, and all of the growers in the highest sales class were certified. USDA did not use the California ratios of certified to uncertified growers in the March 2000 RIA to estimate the number of uncertified growers because the farming structure of California may not be representative of the Nation. For example, California sells at least three times more specialty crops than any other State in the United States and has an unusual registration program that many growers use instead of certification.

USDA made two assumptions about uncertified production for the March 2000 estimate. The first assumption was that the rate of growth in uncertified production is less than the rate for certified farms because certification has value and organic producers would be expected to take advantage of the marketing advantages of certification. This assumption is consistent with California data that showed an increase in the percent of organic farmers obtaining certification between 1996/97 and 1997/98 in virtually every sales class (Klonsky et al. 2000). Second, the emergence of State certification programs with lower certification fees than private certification entities may have encouraged more organic producers to be certified. Based on these assumptions, USDA assumed that the number of uncertified organic producers is about 4,300 in 2000 and will be about 5,000 in 2002, making the total number of farms potentially affected by the rule about 13,650 in 2000 and 17,150 in 2002.

Organic Handlers

Little information exists on the number of organic product handlers, such as organic soup manufacturers, organic food packaging operations, organic food wholesalers, and feed millers. USDA has estimated that there were 600 entities in this category in 1994 (Dunn 1995b). AMS estimated that the growth rate was 11 percent from 1990 through 1994 (Dunn 1995b). More recent data from CDFA registration records suggest a growth rate of about 28 percent (California Department of Health Services 1999). For projection purposes, we use a growth rate of 20 percent and estimate there are about 1,600 in 2000 and there will be about 2,250 handlers in 2002. Reasons for growth include the general increase in organic production and growth in the market for processed organic foods, including multiingredient products. Again, these projections are based on limited data from the early 1990's, and growth may have slowed or increased. These estimates of organic product handlers are slightly higher than the estimates made in the March 2000 RIA because they include about 100 feed millers that were not included in the earlier calculation.

Retail Food Establishments

Retailers of organic food are grocery stores, bakeries and other establishments that

process or prepare raw and ready-to-eat food. Most are not currently subject to either voluntary practices or mandatory standards of the organic industry. Although they are excluded from the certification requirements under the final rule, they are subject to other processing, handling, and other production related requirements of the final rule. Some of the grocery stores in the United States, particularly the natural foods stores, sell processed or prepared organic foods and will be affected by these requirements. USDA does not have an estimate of the number of entities affected.

Foreign Entities

In addition to domestic certifying agents, foreign certifying agents may also apply for accreditation under the NOP. At this time, we have no information regarding the number of foreign certifying agents that may seek USDA accreditation. Foreign applicants will face the same base costs for accreditation as domestic applicants but the overall levels of cost are expected to be higher due to the generally higher costs of foreign travel and per diem expenses for site evaluation and miscellaneous costs such as for translation of documents. For purposes of estimating the paperwork burden described elsewhere, we assume 10 foreign certifying agents will seek and obtain accreditation during the first 3 years of the program.

Benefits of the Final Rule

The benefits of implementing national uniform standards of production and certification include: (1) Providing a common set of definitions on organic attributes and standardizing the manner in which the product information is presented, which may reduce the cost associated with enforcement actions in consumer fraud cases; (2) reduced administrative costs; and (3) improved access to organic markets. Not all benefits that may arise from the rule are quantifiable. Where economic data are available, they may relate to costs and are generally not adequate to quantify economic benefits. The regulatory changes in the final rule are not expected to reduce the benefits from those described under the March 2000 proposed rule.

Information

Potential benefits to consumers as a result of the final rule include providing a common set of definitions on organic attributes and standardizing the manner in which the product information is presented. This standardization may reduce the cost associated with enforcement actions in consumer fraud cases.

Organic products cannot be distinguished from conventionally produced products by sight inspection, and consumers rely on verification methods such as certification to ensure that organic claims are true. Self-policing by certifiers of growers and handlers that are certified has been difficult because some certifiers have been under pressure to use weak standards and lax enforcement procedures in order to keep their producer and processor clients from taking their business to other certifiers (Scowcroft 1998).

Anecdotal evidence suggests that consumer fraud involving organic food does occur, and several States successfully pursued civil and

criminal prosecution of these cases during the 1990's. The Attorney General of Minnesota successfully prosecuted felony charges in 1997 against the president of Glacial Ridge Foods, a wholesale supplier of beans and grains, for repackaging conventionally produced product and selling approximately \$700,000 worth labeled as certified organic (Mergentime 1997). The San Diego City Attorney's office successfully prosecuted felony charges against Petrou Foods, Inc., an organic oil and vinegar distributor, for misbranding conventional product, based on an investigation by the California Department of Health Services (Scott 1997). Also the California Department of Food and Agriculture conducted spot checks of 51 uncertified organic growers during the mid-1990's, based on complaints, and found 32 violations of California's organic standards (Farmers Market Outlook). However, only about half of the States have any organic legislation, and few of those States have laws with enough teeth to permit prosecution of organic fraud. In States without similar laws, the costs associated with remedies via the tort system may be high. The NOP established in this final rule is expected to fill in important State and regional gaps in enforcement in organic fraud cases.

The USDA organic seal will also provide consumers a quick tool to verify that goods offered for sale as organic are in fact organic.

Reduced Administrative Costs

The rule addresses the problem of existing certifying agents using different standards and not granting reciprocity to other certifying agents. By accrediting certifying agents, the rule establishes the requirements and enforcement mechanisms that would reduce inconsistent certification services and lack of reciprocity between certifying agents. In the current system, the certifying agent of a final product is not required to recognize the certification of an intermediate product. Both primary farmers and food handlers may face a risk of being unable to sell a certified organic product when more than one certifying agent is involved. By imposing a uniform standard of certification and production, the costs associated with establishing reciprocity between certifying agents will be eliminated, and the market dampening effects that these costs impose will be eliminated. Industry-wide training costs may also decrease. USDA's uniform standards of production and certification should enable organic inspectors to move more easily from one certifying agent to another than under the current system.

Domestic and International Markets

The final rule is expected to improve access to domestic and foreign markets for organically produced goods. The current patchwork of differing State certification requirements and variable State and private standards has given producers and handlers uneven access to the domestic organic market and to the price premiums associated with this market. Livestock producers, in particular, may have limited their organic production because they lacked access to a State or private organic livestock certification

program or were uncertain about the standards that would be implemented under the NOP.

The final rule could also improve access to EU and other foreign markets for U.S. organic products. For example, the EU may determine that the NOP is acceptable vis-a-vis EU regulation 2092/91. Article 11 of EU Reg. 2092/91 establishes the conditions under which organic products may be imported from third countries and addresses the framework for equivalency. The NOP is a national program that should be acceptable to the EU and other governments. Foreign acceptance of the U.S. national standard would reduce costs of negotiating and documenting shipment by shipment. Reducing these transaction costs may reduce entry costs for U.S. producers to foreign organic markets. These benefits would not accrue until after negotiations for an equivalency agreement have been held and completed successfully, which could be a lengthy process.

An estimated 5 percent of total U.S. sales are from exports. Currently, despite restricted access to the European market, the United States is the most important non-EU supplier of organic products to EU countries (Foreign Agriculture Service (FAS), 1995). Import authorizations have been granted for a number of raw and processed commodities, including sunflowers, buckwheat, beans, sugar, and apples. Demand is strong throughout the European market, and the organic market share was 1–2 percent of total food sales in 1997 (Collins 1999). Medium-term growth rate forecasts range from 5–10 percent for Germany to 30–40 percent for Denmark, and is 20–30 percent in most of the EU countries, according to the International Trade Centre UNCTAD/WTO. However, most analysts are basing their projected future growth rates on straight-line extrapolations of current sales and growth rates without understanding the underlying market mechanisms and price elasticities (Lohr 1998).

Costs of the Final Rule

The costs of the regulation are the direct costs of complying with the specific standards. It is important to note that while some costs associated with accreditation and certification are quantified, costs stemming from other provisions of the final regulations are not. In addition, this is a short-run analysis. The analysis examines the costs that may be incurred through 2002. It is not possible at this time to conduct a longer run analysis because we do not know enough about the fundamental supply and demand relationships to make economically sound long-run projections.

Accreditation Costs

USDA has identified 36 private certifying agents and 13 State programs providing certification in the United States. These 49 entities are considered likely applicants during the first 18 months during which USDA will not charge application fees or hourly fees for accreditation. An unknown number of new entrants to the certifying business may also apply. However, over the last 10 years, the number of certifying agents

does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of certifying agents at about 40–50.

The final rule allows USDA to collect fees from certifying agents for USDA accreditation. The first proposal would have permitted USDA to collect fees from producers and handlers as well, but USDA decided that it would be administratively simpler to collect fees only from certifiers and would enable State programs that want to keep client costs low to be able to do so.

Applicants for accreditation will be required to submit a nonrefundable fee of \$500 at the time of application, which will be applied to the applicant's fees for service account. This means that the \$500 fee paid at the time of application is credited against any subsequent costs of accreditation arising from the initial review and the site evaluation. The \$500 fee is the direct cost to applicants who are denied accreditation based on the initial review of the information submitted with their application. Charges for the site evaluation visit will cover travel costs from the duty station of USDA employees, per diem expenses for USDA employees performing the site evaluation, an hourly charge (per each employee) for services during normal working hours (higher hourly rates will be charged for overtime and for work on holidays), and other costs associated with providing service to the applicant or certifying agent.

At present, the base per diem for places in the United States is \$85 (\$55 for lodging and \$30 for meals and incidental expenses). Per diem rates are higher than \$85 in most large cities and urbanized places, but over half of the current U.S. certifiers are located in places that have an \$85 per diem rate, and that is the rate used to calculate average certifier expenses in table 3. A review of domestic travel by USDA staff during fiscal year 1999 indicates transportation costs ranging from \$500 to \$600 per person. Miscellaneous costs are estimated to add another \$50 to each site visit.

The hourly rate that USDA anticipates charging for accreditation is the rate that USDA currently charges for services under the Quality Systems Certification Program (QSCP). Our preliminary estimate that this rate will be no more than \$95 per hour is presented to give the public some indication of the rate that will be charged following the 18-month transition period. QSCP is an audit-based program administered by AMS, which provides meat producers, handlers (packers and processors), and other businesses in the livestock and meat trade with the opportunity to have special processes or documented quality management systems verified. The procedures for accreditation evaluation are similar to those used to certify other types of product or system certification programs under QSCP.

Accreditation will include verification of adherence to ISO Guide 65 and the regulations. Although much of the site evaluation for accreditation will involve comparisons against ISO Guide 65, additional hours will be required because USDA will be evaluating additional aspects

of the applicant's operation to determine if the applicant is qualified to perform as an accredited agent for the NOP. Based on experience with the QSCP and more limited experience performing audits verifying that certifying agents meet ISO Guide 65, we project that a site evaluation visit for small applicants with a simple business structure will require 3 days of review, and for those large applicants with more complex business structure will require 5 days of review.

USDA will use two reviewers for each site evaluation visit during the 18-month implementation period, as well as for new applicants after that period. One reviewer will come from the QSCP audit staff and will be familiar with the ISO Guide 65 verification; the other reviewer will come from the NOP staff and will be familiar with requirements of the organic program. The two will conduct the site evaluation jointly. Two reviewers will also be needed for the site evaluation visits for the accreditation renewals, which will take place every 5 years. In the proposed rule, USDA had projected that only one reviewer would be needed for site evaluations and renewals that took place after the 18-month implementation period but has changed that projection based on additional experience with the ISO Guide 65 program.

During the 18-month implementation period, applicants will be charged for travel and per diem costs for two persons and for miscellaneous expenses but will not be charged application fees or hourly fees. The estimated expenditures for these initial accreditations is \$1,560–\$2,100, with \$510–\$850 for per diem expenses, \$1,000–\$1,200 for travel expenses, and \$50 for miscellaneous expenses (table 3). The cost of initial site evaluation visits will vary with the cost of travel from the USDA reviewer's duty station to the applicant's place of business. In general, more distant and remote locations will involve higher travel costs.

USDA estimates the costs of a site evaluation visit after the transition period may average \$6,120–\$9,700, depending on the characteristics of the applicant, including \$4,500–\$7,600 for the hourly site evaluation charges that are not billed to the certifier during the first 18 months (table 3). USDA has received appropriated funds to pay for the hourly site evaluation charges only during the first 18 months of the program.

Currently, few private certifying agents are operating with third-party accreditation. Fetter (1999) reports that in a sample of 18 certification programs, four programs were accredited, and one had accreditation pending. All of these were large, private certifying agents. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation. In its first proposal, USDA stated at FR 62:65860, "We are aware that certifiers currently may pay in excess of \$15,000 for accreditation by a private organization." Commenters thought this figure was too high. One commenter, which operates the International Federation of Organic Agriculture Movements (IFOAM) Accreditation Programme under license to IFOAM, stated, "It is possible that the largest programme operating a chapter system with activities in many countries (which is

included in their IFOAM evaluation) paid this amount in their first year. On the other hand the average cost to a medium sized certifier works out at around \$3000 to \$4000 per year." Another commenter stated, "At the present time IFOAM accreditation costs less than \$10,000/year for the largest certifier and \$3–5,000 for smaller certifiers."

The 18-month NOP implementation period affects the distribution of program costs between the organic industry and the taxpayer. Some of the costs of accreditation would be absorbed by the NOP operation budget appropriated by Congress. In effect, the taxpayers are subsidizing the organic industry. Without this subsidy, the total cost of accreditation would approach \$1 million.

The direct accreditation costs to an estimated 59 certifying agents (including all 49 current U.S. certifiers and an estimated 10 foreign certifiers) during the first 18 months following the final rule, are approximately \$92,000 to \$124,000. This figure is derived from the per-firm costs in table 3. In addition, USDA will use appropriated funds to cover approximately \$270,000–\$448,000 in hourly charges for site evaluation. USDA will also use appropriated funds to cover the costs of producing and publishing an accreditation handbook in several languages, translating USDA reports to foreign clients, and developing and funding a peer review panel to evaluate NOP's adherence to its accreditation procedures. And if more than the estimated 59 certifiers apply for accreditation during the first 18 months of the program, USDA will use appropriated funds to cover additional hourly charges for site evaluation.

Private certifying agents and State programs that do not mirror the regulation may incur additional costs to change their programs to adopt the national standards. The discussion on the effect of the regulation on existing State programs is in "State Program Costs." The cost associated with changing existing private certifying programs is not quantified.

Also, certifying agents who have been operating without third party accreditation will face new costs. For certifying agents who currently obtain third-party accreditation, the direct costs of USDA accreditation, which are only incurred every 5 years, may be lower on an annual basis compared to the direct costs for third-party certification of \$3,000–\$5,000 per year indicated by the commenters. The direct costs for certifying agents obtaining accreditation during the first 18 months, when USDA will not impose an application fee or hourly charges, will be limited to travel, per diem, and miscellaneous expenses.

A national accreditation program may shrink the market for a third-party accreditation. Certifying agents will have little incentive to maintain or seek a second accreditation by a private organization unless that accreditation sufficiently enhances the market value of the certifying agent's services. Thus, the market will determine whether other accrediting entities continue to have a U.S. market for their services.

Training programs are currently offered by the Independent Organic Inspectors Association (IOIA), an organization of

approximately 165 organic certification inspectors, and by some of the larger certifying agents (IOIA). Costs to existing certifying agents to provide additional training to other staff are difficult to measure in the absence of information on current staff skill levels or the existence of formal training other than inspector training. Some agencies rely on volunteer staff who may have had no formal training, but the extent of this practice is unknown. AMS intends to offer assistance to certifying agents, producers, and handlers by providing accreditation training for certification agents and other printed material that would enable participants to better understand the regulations. In addition, AMS intends to continue open and frequent communication with certifying agents and inspectors to provide as much information as possible to aid them in fulfilling the requirements of the regulations.

The OFPA requires that private certifying agents furnish reasonable security for the purpose of protecting the rights of participants in the organic certification program. It is expected that there will be costs to certifying agents from these requirements.

Implementation of the final rule will also impose a less tangible cost on some certifiers. Some private certifiers have advertised their program and logo as representing higher standards than other programs. The brand value associated with the logos of these certifiers will be lost when uniform standards are implemented as part of the national program. However, certifiers will still be able to distinguish themselves to clients based on the quality of their services and other characteristics.

A key change was made in the final rule, based on comments to the March 2000 proposal, to make the standard used by certifiers to determine maximum allowable pesticide residues (the level above which a product could not be called organic) consistent with the current industry standard and with NOSB recommendations. In the final rule, the standard will be set at 5 percent of the pesticide residue tolerances calculated by the Environmental Protection Agency (EPA). This change could conceptually reduce costs, but the magnitude of this reduction is uncertain.

Certification Costs

Under the final rule, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating the certification. Under the proposed rule, certifiers could charge a maximum of \$250 at the time of application, but under the final rule, certifiers are not limited in the amount of certification fees that they may charge at the time of application.

Some States charge minimal fees for certification by subsidizing operating costs from general revenues. The majority of

certifying agents structure their fee schedules on a sliding scale based on a measure of size, usually represented by the client's gross sales of organic products but sometimes based on the acres operated (Fetter 1999 and Graf and Lohr 1999). Some certifying agents charge an hourly rate for inspection and audit services.

Graf and Lohr have applied fee schedules provided by ten certifying agents to four hypothetical farms, small, medium, large, and a super farm. Tables 2A and 2B summarizes the fees that Graf and Lohr found by applying schedules of each certifying agent to hypothetical farms. Total first-year costs and subsequent-year (renewal) costs for certification are shown. The average cost for each size class should be interpreted with care because it is not weighted by the number of clients certified. In their study, the Texas Department of Agriculture program is the low-cost certifying agent for all-size operations. The high-cost certifying agent differs across farm sizes. None of these certification programs mentions costs for residue testing, which the NOP will require in the form of preharvest testing when there is reason to believe that agricultural products have come into contact with prohibited substances. Preharvest testing is expected to be infrequent. Some certifying agents currently require soil nutrient testing and water quality testing. The estimated total initial costs for a producer or handler to become certified are presented in table 3.

We have not extended the average costs reported in Tables 2A and 2B to aggregate certification costs for all organic farms because the number of organic farms is not known with precision, nor is their geographic location, and there are no data to distribute the population of organic farms across size classes. The data from California suggest that a large number of small farmers produce and market organic goods without third-party certification, but those data may not be representative of the national trend. Although many of the smallest farms would qualify for the small farm exemption from certification, if consumers accept the labeling practices required by this final rule, small farmers may obtain certification to stay in the organic market, which may involve some cost.

In response to comments, the March 2000 proposal was changed to provide that if a conflict of interest is identified within 12 months of certification, the certifying agent must reconsider the application and may reinspect the operation if necessary. Additionally, if a conflict of interest is identified, the certifying agent must refer the operation to a different accredited certifying agent. These provisions would likely increase costs to certifiers; however, the magnitude of this increase is unknown.

Production and Handling Costs

Producers and handlers currently active in the organic industry may bear costs under the national standards. We believe that while most provisions of the program mirror current industry practices, there are some differences. In addition to the cost associated with becoming familiar with the national program, any adjustments stemming from these differences will result in costs. These

costs were qualitatively discussed in the March 2000 RIA for major provisions of the rule and are described below. The March 2000 proposal adhered closely to recommendations from the NOSB and largely reflected current industry standards. Marginal changes have been made in the final rule in response to comments on the March 2000 proposal. These changes have been made in concert with NOSB recommendations and, in general, have been made to clarify or add flexibility to producer and handler provisions or to make them better reflect current industry standards.

Producers

Producers of organic food will face numerous provisions that will regulate their production methods. As indicated in the Baseline section, many of the requirements are currently followed by certified organic farmers. Farming operations that are not certified but are registered with a State government, such as California, receive copies of the State laws to which they must comply. The costs associated with adjusting to provisions in the final rule may be minimal for certified and State-registered growers but may be more substantial for noncertified organic producers that do not follow a specific set of guidelines or regulations. Some organic producers are neither certified nor registered and, therefore, may not practice the requirements in the final rule. Major provisions of the final rule—the withdrawal period required for land to be free of prohibited substances, National List, animal drug use, and residue tests—are discussed to illustrate costs; other provisions may also impose additional costs.

A 3-year withdrawal period, during which prohibited materials cannot be applied to a field to be certified as organic, is currently required by most private and State organic standards, and the final rule also specifies a 3-year period. The effect of this provision on the currently certified organic farming operations may be minimal, but the effect on farming operations that are neither certified nor registered may be significant. Farming operations that have completed a 3-year withdrawal period will not be affected by this requirement. To stay in the organic industry, those who have not completed the 3-year period must comply with this requirement. They may incur the cost of organic production for a significant length of time, yet not be allowed to sell their products as organic. Hence, some small organic operations may exit the industry.

The impact of the National List, which lists allowed synthetic substances and prohibited nonsynthetic substances that may or may not be used in organic production and handling operations, will be determined by how the national standards differ from current certification standards and from actual practice. Lists of approved synthetic materials, including soil amendments and pesticides, vary from one certification program to another, but a detailed analysis of specific differences in the various existing materials lists shows them to be overlapping in most cases with each other and with the National List. The degree of overlap should mitigate the costs for certified operations, but

farming operations, particularly those that aren't certified, may need to make some adjustments to comply with the list. These adjustments will impose costs on these operations. The magnitude of the costs resulting from these adjustments is not quantified.

Where livestock standards have been adopted by existing State programs and by private certifying agents, most prohibit the use of animal drugs except for the treatment of a specific disease condition, and use of animal drugs is generally prohibited within 90 days prior to the sale of milk or eggs as organic. Some State and private certifiers allow the use of animal drugs in animals for slaughter under certain conditions, while others prohibit the use of animal drugs. The standards in the final rule would prohibit the sale as organic of edible products derived from an animal treated with antibiotics or other unapproved substances. The standards may not differ from existing State or private standards in prohibiting the use of drugs on healthy animals. However, the effect of this provision may differ among certified and registered organic farms. The effect on the certified farming operations is unknown. We assume that this provision may have costs, but the magnitude of these costs is not quantified.

Additional costs may be imposed by several further changes to the March 2000 proposal. These changes involve the use of treated lumber, confinement requirements, and the commercial availability of ingredients in products labeled "organic."

The replacement of lumber treated with prohibited substances that comes into contact with soil, crops, or livestock under organic management with treated lumber is now specifically prohibited in organic systems. Since the use of lumber treated with prohibited substances for the purpose of preventing degradation is not a common practice in livestock production, this prohibition is not expected to increase producer costs substantially. The exact magnitude of any increase is uncertain and mainly dependent upon the number of producers seeking organic certification that currently use treated lumber in their operations and are planning to replace that lumber.

The confinement provisions in the March 2000 proposal have been slightly modified. Access to the outdoors is now an explicitly required element for all organically raised livestock. We expect this change to have a minor impact on overall producer costs, since we assume most producers raising organic livestock already provide access to the outdoors. Additionally, the term, "pasture," has been defined to emphasize that livestock producers must manage their land to provide nutritional benefit to grazing animals while maintaining or improving soil, water, and vegetative resources of the operation. To the extent producers desiring to raise organic livestock do not currently manage pasture in this manner, we expect livestock production costs to increase.

The organic plan now requires using organically produced minor agricultural ingredients unless not commercially available. This applies to the previously

allowed 5-percent nonorganic agricultural and other ingredients in products labeled "organic." Handlers of organically produced minor ingredients, especially herbs and spices, are likely to benefit from this market incentive, while producers of nonorganic minor ingredients will likely be adversely affected. Producers will also realize a burden associated with providing the documentation of commercial availability for ingredients in the 5-percent component. Since the criteria to determine commercial availability will be developed after additional comments and information are considered, the magnitude of the cost and benefit implications from this standard are currently unquantifiable but will likely be largely dependent upon the stringency of the developed criteria.

Producers will also have administrative costs for reporting and recordkeeping, although producers who currently are active in the organic industry already perform most of these administrative functions, and additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final rule. The annual reporting and recordkeeping burden on producers is estimated at 24 hours for certified producers and 1 hour of recordkeeping for small producers who choose to operate as exempt entities and is valued at \$23 per hour.

Other provisions of the final rule, such as those on residue testing, livestock housing and feed, and health care practices, may vary enough from those followed by some growers that they may impose costs due to the variability in current housing, feed, and health care practices, but lacking information, we have not quantified these costs.

There were also several key changes made in the final rule, based on comments to the March 2000 proposal, that will add flexibility to producer standards. A specific type of production facility was required for composting manure in the proposal, and this provision has been modified to ensure that manure is adequately composted while allowing variation in the type of facility that is used. Also, the transition period of a dairy operation to make a whole-herd conversion to organic production has been reduced in order to make conversion affordable for a wider range of dairy farms, including smaller operations. Finally, the requirement that slaughter stock sold, labeled, or represented as organic be under continuous organic management from birth was changed to require continuous organic management from the last third of gestation. This change is also expected to provide possible cost savings and added flexibility for producers.

Handlers

Handlers of organic food are defined and regulated differently across different certifying agents and States. Due to this variability, handlers may incur some cost associated with complying with the requirements of the regulation. Several key changes were made in the final rule, based on comments to the March 2000 proposal, to make handler standards more consistent with current industry standards. The proposal prohibited the addition of sulfites to wine as

required by OFPA. The statute has been changed since March, and the final rule will permit added sulfites in wine labeled "made with organic grapes," consistent with industry standards and NOSB recommendations.

Also, the March proposal required products labeled "made with organic ingredients" to have ingredients that were at least 50 percent organic, and this threshold has been raised to 70 percent in the final rule. Some certifiers set their thresholds at 50 percent, others at 70 percent, while others restrict labeling to individual ingredients only. The international industry standard outside the United States is set at 70 percent. The threshold is set at 70 percent in the final rule in response to comments received on the proposal and to be consistent with international standards, which will help ease export of U.S. organic product into those markets. Alternatively, to the extent handlers do not currently meet the 70-percent threshold to label products "made with organic ingredients," handlers may incur additional costs to reach the threshold or exit the industry. The magnitude of those effects is unknown.

In addition to the labeling requirement, a handler's current use of nonsynthetic and synthetic substances may change in response to the final rule. The March 2000 proposal provided for the use of any prohibited substance to prevent or control pests. This provision has been changed to first limit the use of nonsynthetic and synthetic substances to substances which are on the National List before allowing the use of any synthetic substance. To the extent to which handlers are now required to consider substances on the National List before using a prohibited substance and these substances on the National List are priced differently from the substance otherwise used, handlers may incur a change in production costs. This requirement may increase costs on handlers, but the magnitude of this increase is unknown.

In addition, the commercial availability requirement in the final rule, described in the producer costs section, may also create a burden on handlers to consistently apply the standard. To the extent to which sourcing organically produced ingredients in excess of 95 percent of the finished product is more expensive than sourcing nonorganically produced ingredients, handlers seeking the "organic" label for their products will incur additional costs. As previously described, the magnitude of the cost implications from this standard is currently unquantifiable but will likely be largely dependent upon the stringency of the standard that is developed.

Handlers will also have administrative costs for reporting and recordkeeping, although handlers who currently are active in the organic industry already perform most of these administrative functions, and additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final rule. The annual reporting and recordkeeping burden on handlers is estimated at 63 hours for certified handlers and 1 hour of recordkeeping for small handlers who choose to operate as exempt entities and is valued at \$23 per hour.

Retail Food Establishments

Most retailers are not currently subject to either voluntary practices or mandatory standards of the organic industry. Retailers that have organic processing operations, such as organic food delis and bakeries, are not required to be certified in the final rule. However, retailers will be subject to requirements such as prevention of contamination of organic products with prohibited substances, and commingling organic with nonorganic products. Obtaining certification and complying with these provisions will incur some cost.

Labeling Costs

Certified handlers will have to comply with requirements regarding the approved use of labels. In addition, any producers, handlers, and retailers who are not currently certified but who package organic products are also subject to the labeling requirements. The estimated annual cost for handlers to determine the composition of 20 products to be reported on labels is \$1,647,000. This figure is based on an average of 1 hour per product per handler and an hourly cost of \$27. Similarly, certified handlers will have to design their labels to comply with the regulation. This is expected to take 1 hour per label at \$27 per hour for a compliance cost of \$1,647,000. Total label costs for handlers are \$3.3 million. Any changes to existing labels and new labels that need to conform to the regulation will incur a cost. The costs associated with these activities are not quantified. Hence, the lower bound on the labeling cost is approximately \$4 million.

State Program Costs

The national program may impose additional costs on States by requiring changes in their existing programs. The rule encompasses most of the principles of existing State programs. However, there are also departures.

Where State standards are below Federal standards or where elements of the Federal standards are missing from a State program, these States would be required to make changes in their programs that they might otherwise not make. Where State programs have standards in addition to the Federal standards and they are not approved by the Secretary, States also would be required to make changes in their programs. States without organic standards or whose current standards either would conform to those of the national program or would be approved by the Secretary would not incur additional costs resulting from required changes. Currently, USDA cannot predict which States may be required to adjust their existing programs.

States that conduct certification activities will be charged for accreditation, something none of them pay for now. The cost associated with this provision is discussed in the Accreditation section.

Enforcement costs

Enforcement costs will fall upon USDA's NOP, States operating State organic programs, and on State and private certifying agents. Certifying agents will review clients' operations and will notify clients of

deficiencies. Certifying agents can initiate suspension or revocation of certification. Certifying agents will be aware of these overhead costs, and we assume that they will establish fee schedules that will cover these costs. Actual costs to certifying agents for enforcement activities will depend on the number of clients, how well informed clients are of their obligations, and client conduct. State certifying agents will face the same obligations and types of costs as private certifying agents.

In States operating State organic programs (SOP), State enforcement costs are costs associated with ensuring that certified operations fulfill their obligations. These States will bear the costs of investigating complaints, monitoring use of the State organic seal and organic labeling, and taking corrective action when needed. These States will bear costs related to reviewing an applicant's or certified operation's appeal and for administrative proceedings. Many of these activities are already a routine part of the certification program in States that have programs, and USDA will fill in gaps in enforcement in States that choose not to have programs.

USDA's enforcement costs are costs associated with ensuring that certifying agents fulfill their obligations. In States without an organic program, USDA will bear the costs of investigating complaints, monitoring use of the USDA organic seal and organic labeling, and taking corrective action when needed. USDA will bear costs related to reviewing an applicant's or certified or accredited operation's appeal and for administrative proceedings. USDA expects to effectively carry out its enforcement responsibilities using funds that are already allocated for operating the NOP. To the extent to which we did not estimate the likely noncompliance rate, the cost associated with enforcement remains unknown.

Reporting and Recordkeeping Costs

The Paperwork Reduction Act of 1995 requires an estimate of the annual reporting and recordkeeping burden of the NOP. The estimated annual reporting and recordkeeping burden reported is approximately \$13 million. This figure should be understood within the context of the requirements of the Paperwork Reduction Act. The Paperwork Reduction Act requires the estimation of the amount of time necessary for participants to comply with the regulation in addition to the burden they currently have. Information gathered by AMS in auditing activities in conjunction with ISO Guide 65 verifications leads us to believe that the paperwork burden on current certifying agents and certified operators will be 10 to 15 percent greater than their current business practices as a result of this final rule.

Certifying Agents. The regulation will impose administrative costs on certifying agents for reporting and recordkeeping. The actual amount of the additional administrative costs that would be imposed by the rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Certifying agents that currently

are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the regulation. An estimate of the cost of compliance is the annual reporting and recordkeeping burden documented in the Paperwork Reduction Act of 1995 analysis. Table 4 shows the estimated annual costs for certifying agents. Certifying agencies each have an estimated burden of 1,068 hours valued at roughly \$27,729.

The following list describes several of the most significant administrative requirements or optional submissions and the probable resources required for compliance. Details on the reporting and recordkeeping burdens estimated for each item are in the paperwork analysis.

1. A list of farmers, wild-crop harvesters, and handlers currently certified. This information can be compiled from existing records. After implementation, certifying agents will be required to submit on a quarterly basis a list of operations certified during that quarter.

2. A copy of procedures used for certification decisions, complying with recordkeeping requirements, maintaining confidentiality of client's business-related information, preventing conflicts of interest, sampling and residue testing, training and supervising personnel, and public disclosure of prescribed information concerning operations they have certified and laboratory analyses. These policies may have to be created or modified to conform to the regulation.

3. Documentation on the qualifications of all personnel used in the certification operation, annual performance appraisals for each inspector and personnel involved in the certification, and an annual internal program evaluation. Existing certifying agents may already perform these operations. New certifying agents will have to establish procedures to achieve these things.

4. Documentation on the financial capacity and compliance with other administrative requirements (e.g., fee structure, reasonable security to protect the rights of the certifying agent's clients as provided in the NOP, and business relationships showing absence of conflicts of interest). Some of this information can be compiled from existing records, e.g., fee schedules, and some may be generated from other sources.

5. Copies must be submitted to USDA of all notices that are issued on certification denial, noncompliance, and suspension or revocation of certification. This requirement will be fulfilled simultaneously with sending notices to applicants or clients.

6. An annual report to the Administrator including an update of previously submitted business information, information supporting any requested changes in the areas of accreditation, and steps taken to respond to previously identified concerns of the Administrator regarding the certifying agent's suitability for continued accreditation. The annual report requirement will draw on records created in the normal course of business.

7. Retention of records created by the certifying agent regarding applicants and

certified operations for not less than 10 years, retention of records obtained from applicants and certified operations for not less than 5 years, and retention of other records created or received for USDA accreditation for not less than 5 years. This activity requires records, database management capabilities, and resources (storage space, file cabinets, electronic storage, etc.). In an informal inquiry, AMS found that most existing certifying agents currently retain records for at least 10 years and use both electronic and paper storage. We believe that this requirement will not pose an additional burden on existing certifying agents.

8. Public access to certification records, such as a list of certified farmers and handlers, their dates of certification, products produced, and the results of pesticide residue tests. This requirement will have minimal impact given the requirements for retaining records.

9. Providing program information to certification applicants. To comply with this requirement, certifying agents may need to modify existing standards and practices. The criteria for qualified personnel in the rule may likely result in an increase in labor costs for some existing certifying agents and, initially, an increase in training costs. The amount of additional costs to these certifying agents would depend on the level of expertise among current certification agency staff, the extent to which certifying agents currently rely on volunteers, and the current costs of training certification staff.

Producers and Handlers. The regulation will impose administrative costs on producers and handlers for reporting and recordkeeping. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. An estimate of the cost of compliance is the annual reporting and recordkeeping burden documented in the Paperwork Reduction Act of 1995 analysis.

The following list describes several administrative requirements or optional submissions and the probable resources required for compliance.

1. Establish, implement, and update annually an organic production or handling plan. Organic plans are a standard feature in the organic industry and are required by certifying agents. Thus, producers and handlers who are already involved in organics can rely on their current plan with revisions as needed to meet elements of the national program which are new to them or differ from their current practice. Although producers and handlers are generally aware of the goals of organic plans, current practice may fall short of the rigor that will be required by the national program. New producers and handlers will have higher costs because they will have to prepare a plan from scratch.

2. Maintain records pertaining to their organic operation for at least 5 years and allow authorized representatives of the Secretary, the applicable State organic program's governing State official, and the certifying agent access to records. Existing organic producers and handlers maintain records. New producers and handlers will have to develop records systems. Access is expected to be infrequent, will require little time of the certified entity, and will not require buildings or equipment other than what is required for storing records.

3. Notify the certifying agent as required (e.g., when drift of a prohibited substance may have occurred) and complete a statement of compliance with the provisions of the NOP. Notifications are expected to be infrequent.

The total reporting burden includes creation and submission of documents. It covers the greatest amount of reporting burden that might occur for any single creation or submission of a document during any one of the first 3 years following program implementation; i.e., 2000, 2001, and 2002. The total estimated reporting burden reflects the average burden for each reporting activity that might occur in 1 year of this 3-year period.

The total recordkeeping burden is the amount of time needed to store and maintain records. For the purpose of measuring the recordkeeping burden, the year 2002 is used as the reporting year for which the largest number of records might be stored and maintained.

The annual reporting and recordkeeping burden on producers, handlers, and certifying agents is summarized in table 4. The annual burden on certified producers is estimated at 24 hours and \$552. Certified handlers have an estimated burden of 63 hours valued at \$1,449. The burden on small producers and handlers who choose to operate as exempt entities is minimal, 1 hour of recordkeeping valued at \$23. If this cost is applied to the total estimated number of affected producers, the reporting and recordkeeping cost would be \$5,260,100 in 2000 and \$6,835,554 in 2002. By applying this cost figure to the estimated total number of affected handlers, the reporting and recordkeeping cost would be \$2,143,002 in 2000 and \$3,013,552 in 2002.

Barriers to Entry—Importers of Organic Products

Currently, there are no Federal restrictions on importing organic products to the United States in addition to those regulations applying to conventional products. If the imposition of the NOP decreases the importation of organic food into the United States, then this regulatory action may result in some cost.

Small Business Ramifications

USDA's final rule has an 18-month period during which applicants for accreditation would not be billed for hourly services. The rationale for this transition period is to reduce the costs to certifying agents and, thus, increase the prospect that certifying agents, producers, and handlers will be able to afford to participate in the national

program. The choice of 18 months is intended to provide sufficient time for parties desiring accreditation to submit their application and prepare for a site evaluation.

USDA will operate the program partially with appropriated funds, in effect sharing the cost of the program between taxpayers and the organic industry, to respond to public concerns regarding the effects of the regulation on small businesses. Thousands of comments were received opposing the first proposal's fee provisions with most focusing on the substantial impact on small certifying agents.

Congress has expressed public policy concern with the impacts of regulations on small entities generally and with the impacts on the NOP regulations on small entities particularly. The Small Business Regulatory Enforcement Fairness Act of 1996 and the Regulatory Flexibility Act express Congressional concern regarding regulatory burden on small businesses. The Report from the Committee on Appropriations regarding the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2000, includes the following language (U.S. Senate 1999):

"The Committee continues to recognize the importance of organic markets for small farmers and fishermen. The Committee expects the Secretary to construct a national organic program that takes into consideration the needs of small farmers and fishermen.

* * * Furthermore, the Committee expects that of the funding available for the National Organic Program, necessary funds should be used to offset the initial costs of accreditation services, a subsidy necessary due to the lack of expertise in the Department of Agriculture in the areas of organic accreditation and insufficient data on the industry."

Certifying agents applying for accreditation during the first 18 months following the final regulation will face lower direct costs than subsequent applicants. The cost for later applicants for accreditation will be higher because they will have to pay a \$500 application fee and hourly charges for completing their site evaluation. The requirement for accreditation was established in the OFPA in 1990 and the accreditation program was part of the 1997 proposal. Because in this final rule, USDA is using appropriated funds to cover some of the costs of initial accreditation during the first 18 months of the program, certifying agents may set lower fees initially benefiting the producers and handlers who are certified during this period.

It is important to note that many small organic operations may not be certified currently. In California, for example, many small farms are registered but not certified. Even if certifying agents pass on the cost savings of the 18-month period provision to applicants for certification, the cost of certification may be higher than the cost of registration. Hence, becoming a certified operation for small organic producers and handlers may be more costly than the current practices.

The costs imposed on small operations may be mitigated by a \$5000 certification exemption to aid the smallest organic operations. However, these operations are

still subject to other requirements of the regulation. To the extent that these requirements differ from their current practices, complying with the national standards may be costly for exempt operations.

In addition, the certification exemption allowed under the regulation includes limits on what an exempt operation may do. Without the certification, small organic operations may not display the USDA seal and may not use a certifying agent's seal. If the consumers of organic food view the seals as important information tools on organic food; that is, if consumers of organic products insist on only certified organic products, the inability of small operations to display these seals may prevent them from realizing the price premiums associated with certified organic products.

Industry Composition

The imposition of the national standards may change the composition of the organic industry. Even with the small business exemptions, some small organic operations may choose to exit the industry, and small organic operations may also be discouraged from entering the industry, resulting in a higher concentration of larger firms. On the other hand, it may be easier for small operations to comply with certain NOP standards, such as the livestock standards that prohibit confinement production systems and require 100 percent organic feed. And State and Federal certification and conservation cost-share programs and other government programs may help lower the impact on small producers.

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TABLE 1.—U.S. ORGANIC PRODUCT SALES, 1990-99

(\$ billions)

Year	Export	Direct	Export/ direct subtotal	Mass market	Natural foods stores	Natural foods stores (1999 \$)	Total sales	Total sales (1999 \$)
1990	1	1.27
1991	0.04	0.27	0.31	0.09	0.85	1.04	1.25	1.53
1992	0.07	0.32	0.39	0.12	1.03	1.22	1.54	1.83
1993	0.11	0.36	0.47	0.14	1.29	1.49	1.90	2.19
1994	0.20	0.39	0.60	0.17	1.54	1.73	2.31	2.60
1995	1	1	0.71	0.21	1.87	2.04	2.79	3.05
1996	1	1	1	1	3.5	3.72
1997	2
1998	3.28	3.35
1999	4.00	4.00

Source: *Natural Foods Merchandiser*, *New Hope Communications*.—= Not reported.

¹ New Hope Communications reported a combined estimate for export and direct sales in 1995 and reported a different set of subcategories in 1996 and has reported only on sales in natural foods stores since 1996.

² New Hope Communications did not estimate natural product store sales in 1997, but the Hartman Group estimated these sales at \$4.9 billion.

TABLE 2A.—FIRST-YEAR CERTIFICATION COSTS, FROM GRAF AND LOHR ANALYSIS

(dollars)

Certifying agent	Small farm	Medium farm	Large farm	Super farm
CCOF	850	1,750	4,850	51,250
FVO	698	1,737	5,214	51,550
FOG	810	1,860	4,860	51,210
NOFA-VT	335	535	585	585
NC/SCS	700	900	1,000	2,000
OGBA	1,290	3,300	12,300	33,296
OTCO-In	608	1,603	2,517	150,300
OTCO-Out	768	1,698	2,852	12,052
OCIA-WI	315	1,590	6,090	75,090
OCIA-VA	258	320	495	1,745
TDA	90	155	200	575
WSDA	480	1,555	3,040	12,480
Average cost	579	1,414	3,623	33,276

Notes:

CCOF—California Certified Organic Farmers

FVO—Farm Verified Organic

FOG—Florida Certified Organic Growers & Consumers

NOFA-VT—Northeast Organic Farming Association—Vermont

NC/SCS—NutriClean/Scientific Certification Systems

OBBA—Organic Growers and Buyers Association

OTCO-In—Oregon Tilth Certified Organic, inside Oregon

OTCO-Out—Oregon Tilth Certified Organic, outside Oregon

OCIA-WI—Organic Crop Improvement Association, Wisconsin chapter

OCIA-VA—Organic Crop Improvement Association, Virginia chapter

TDA—Texas Department of Agriculture

WSDA—Washington State Department of Agriculture

Small farm—25 acres with annual sales of \$30,000.

Medium farm—150 acres with annual sales of \$200,000.

Large farm—500 acres with annual sales of \$800,000.

Super farm—3,000 acres with annual sales of \$10,000,000.

TABLE 2B.—SUBSEQUENT-YEAR CERTIFICATION COSTS, FROM GRAF AND LOHR ANALYSIS
(dollars)

Certifying agent	Small farm	Medium farm	Large farm	Super farm
CCOF	425	1,300	4,350	50,550
FVO	510	1,499	4,851	51,187
FOG	325	845	2,525	25,525
NOFA-VT	300	500	550	550
OTCO-In	454	1,611	2,362	11,363
OTCO-Out	424	1,353	2,207	11,208
OCIA-WI	290	1,565	6,065	75,065
OCIA-VA	233	295	470	1,720
TDA	90	155	200	515
WSDA	330	1,375	2,800	12,000
NC/SCS	700	900	1,000	2,000
Average cost	371	1,036	2,489	21,971

Notes:

CCOF—California Certified Organic Farmers

FVO—Farm Verified Organic

FOG—Florida Certified Organic Growers & Consumers

NOFA-VT—Northeast Organic Farming Association—Vermont

NC/SCS—NutriClean/Scientific Certification Systems

OBBA—Organic Growers and Buyers Association

OTCO-In—Oregon Tilth Certified Organic, inside Oregon

OTCO-Out—Oregon Tilth Certified Organic, outside Oregon

OCIA-WI—Organic Crop Improvement Association, Wisconsin chapter

OCIA-VA—Organic Crop Improvement Association, Virginia chapter

TDA—Texas Department of Agriculture

WSDA—Washington State Department of Agriculture

Small farm—25 acres with annual sales of \$30,000.

Medium farm—150 acres with annual sales of \$200,000.

Large farm—500 acres with annual sales of \$800,000.

Super farm—3,000 acres with annual sales of \$10,000,000.

TABLE 3.—COSTS OF ACCREDITATION AND CERTIFICATION

Estimated costs to certifying agents during first 18 months	
Application fee ¹	\$0.
Site evaluation costs (two person team):	
Per diem (3 to 5 days at \$85/day)	\$510 to \$850.
Travel (domestic)	\$1,000 to \$1,200.
Hourly charges (not billed during the first 18 months)	\$0.
Miscellaneous charges (copying, phone, and similar costs)	\$50.
Total	\$1,560 to \$2,100.
Estimated costs to certifying agents for initial accreditation after first 18 months	
Site evaluation costs (two person team):	
Per diem (3 to 5 days)	\$510 to \$850.
Travel (domestic)	\$1,000 to \$1,200.
Hourly charges (24 to 40 hours at \$95/hour)	\$4,560 to \$7,600.
Miscellaneous charges (copying, phone, and similar costs)	\$50.
Total	\$6,120 to \$9,700.
Annual review fees for certifying agents (2 to 8 hours at \$95/hour) ²	\$190 to \$760.
Estimated costs to producers for certification ³	
Certification fee (renewals)	\$730.
Estimated costs to handlers for certification ⁴	
Certification fee (initial certification)	\$2,337.
Certification fee (renewals)	\$1,665.

¹ Nonrefundable fee that will be applied to the applicant's fee-for-service account.² Certifying agents are required to submit annual reports to USDA. Review of these reports is expected to range from 2 to 8 hours at an approximate rate of \$95 per hour.³ Estimated certification fees are calculated from Graf and Lohr 1999 which, for a selection of certification agents, provides certification costs for four hypothetical farm sizes: (1) small farm (family farm): 25 acres, \$30,000 annual sales, 5 hours to certify; (2) medium farm (cottage industry): 150 acres, \$200,000 annual sales, 6 hours to certify; (3) large farm (commercial farm): 500 acres, \$800,000 annual sales, 8 hours to certify; and (4) super farm: 3,000 acres, \$10,000,000 annual sales, 16 hours to certify. Our estimated certification fees only include those charged for small and medium farms because most organic producers fall into these categories as defined by Graf and Lohr. In the 1997 OFRF survey, 90 percent of respondents had gross organic farming income of less than \$250,000, with 82 percent less than \$100,000.

The average current certification cost for most organic producers is about \$1,025 for the first year of certification (\$579 for small and \$1,414 for medium farms) and about \$705 for subsequent years (\$371 for small and \$1,036 for medium farms). Approximately \$25 is added to cover the costs associated with the National Organic Program for an estimated first-year certification fee of \$1,000 and subsequent-year certification fee of \$730 for producers. Larger producers could expect higher fees.

⁴ Because Graf and Lohr do not estimate certification fees for handlers, we estimate these fees by applying a ratio of handler-to-producer certification fees from the regulatory impact assessment from 1997. The ratio is 2:28 and results in estimated fees of \$2,337 and \$2,665, respectively.

TABLE 4.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Type of respondent	Annual hourly per respondent	Hourly rate	Annual cost
Certified producer	24	\$23	\$552
Certified handler	63	23	1,449
Exempt producers and handlers	1	23	23
Certifying agency	1,068	27	27,729

Note: Estimates derived from Paperwork Reduction Act of 1995 analysis.

Appendix B—Unfunded Mandates Reform Act

This rule has been reviewed under the Unfunded Mandates Reform Act (Pub. L. 104–4). The Act requires that agencies prepare a qualitative and quantitative assessment of the anticipated costs and benefits before issuing any rule that may result in annual expenditures by State, local, and tribal governments, in the aggregate, or by the private sector of \$100 million (adjusted annually for inflation) in any 1 year. According to the Act, the term, “Federal mandate,” means any provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments or the private sector, except a duty arising from participation in a voluntary Federal program.

The National Organic Foods Production Act (OFPA) of 1990 mandates that the Secretary develop a national organic program to accredit eligible governing State officials or private persons as certifying agents who would certify producers or handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. The OFPA also permits a governing State official to voluntarily establish a State organic program (SOP) if the program is approved by the Secretary and meets the requirements of the OFPA. The OFPA does not require that States establish their own SOP’s or that State, local, or tribal governments or the private sector become accredited; therefore, the OFPA is not subject to the Unfunded Mandates Reform Act because it is a voluntary program.

Although the U.S. Department of Agriculture has determined that this rule is not subject to the Unfunded Mandates Reform Act, USDA has sought to consider the rule’s impact on various entities. USDA prepared a Regulatory Impact Assessment (RIA) that is discussed in the section entitled “Executive Order 12866” (also attached as an appendix to this regulation). The RIA consists of a statement of the need for the action, an examination of alternative approaches, and an analysis of the benefits and costs. Much of the analysis is necessarily descriptive of the anticipated impacts of the rule. Because basic market data on the prices and quantities of organic goods and services and the costs of organic production are

limited, it is not possible to provide quantitative estimates of all benefits and costs of the rule. The cost of fees and recordkeeping required by USDA are quantified, but the anticipated benefits are not. Consequently, the analysis does not contain an estimate of net benefits.

The analysis employed in reaching a determination that this rule is the least costly and least burdensome to the regulated parties is discussed in the sections entitled “The Regulatory Flexibility Act and the Effects on Small Businesses” and “Paperwork Reduction Act of 1995.” The rule has been designed to be as consistent as possible with existing industry practices, while satisfying the specific requirements of the OFPA.

We have had numerous occasions during which to communicate with various entities during the development of the rule; States, for example. Currently, there are 32 States with some standards governing the production or handling of organic food and 13 States with organic certifying programs. Representatives of State governments have participated in public meetings with the National Organic Standards Board, while the NOP staff has made presentations, received comments, and consulted with States and local and regional organic conferences, workshops, and trade shows. States have been actively involved in training sessions for organic inspectors; public hearings concerning standards for livestock products during 1994; a national Organic Certifiers meeting on July 21, 1995; a USDA-hosted meeting on February 26, 1996; a State certifiers meeting in February 1999; and an International Organization for Standardization (ISO) 65 assessment training session for certifiers in April-May 1999. More detail about contact with States regarding this rule is in the Federalism section. It is unknown at this time how many States, if any, might voluntarily establish their own SOP’s pursuant to the OFPA and the regulations.

Appendix C—Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without

unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action.

1. Need for and objectives of the National Organic Rule.

Currently, organic certification is voluntary and self-imposed. Members of organic industries across the United States have experienced numerous problems marketing their organically produced and handled agricultural products. Inconsistent and conflicting organic production standards may have been an obstacle to the effective marketing of organic products. There are currently 36 private and 13 State organic certification agencies (certifying agents) in the United States, each with its own standards and identifying marks.

Some existing private certifying agents are concerned that States might impose registration or licensing fees which would limit or prevent private certification activities in those States. Labeling problems have confronted manufacturers of multiingredient organic food products containing ingredients certified by different certifying agents because reciprocity agreements have to be negotiated between certifying agents. Consumer confusion may exist because of the variety of seals, labels, and logos used by certifying agents and State programs. Also, there is no industrywide agreement on an accepted list of substances that should be permitted or prohibited for use in organic production and handling. Finally, a lack of national organic standards may inhibit organic producers and handlers in taking full advantage of international organic markets and may reduce consumer choices in the variety of organic products available in the marketplace.

To address these problems in the late 1980’s, the organic industry attempted to establish a national voluntary organic certification program. At that time, the industry could not develop consensus on the standards that should be adopted, so Congress was petitioned by the Organic Trade Association to establish national standards for organic food and fiber products.

In 1990, Congress enacted the Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 *et seq.*) (OFPA). The OFPA

requires all agricultural products labeled as "organically produced" to originate from farms or handling operations certified by a State or private agency that has been accredited by USDA.

The purposes of the OFPA, set forth in section 2102 (7 U.S.C. 6501), are to: (1) Establish national standards governing the marketing of certain agricultural products as organically produced products; (2) assure consumers that organically produced products meet a consistent standard; and (3) facilitate commerce in fresh and processed food that is organically produced. The National Organic Program (NOP) is the result of the OFPA.

Recently, the Organic Trade Association published American Organic Standards, Guidelines for the Organic Industry (AOS). However, not all participants in the organic industry elected to participate in developing the AOS. Many certifying agents preferred to wait for implementation of the national standards, and some certifying agents disagree with portions of the AOS. For these reasons, USDA will implement a regulation for the NOP.

2. Summary of the significant issues raised by public comments in response to the Initial Regulatory Flexibility Analysis (IRFA), a summary of agency assessment of such issues, and a statement of any changes made in the final rule as a result of such comments.

Although we received many individual comments in reference to the proposed rule's IRFA, they were, for the most part, variations of several form letters. Most of the concern on the part of commenters regarded the fees that small certifying agents would be subject to under the rule.

Comments Accepted

(1) We received numerous comments to the effect that the fees, recordkeeping, and paperwork requirements for producer and handler certification must be kept as low as possible while still offering a quality certification program. We believe that we have made every effort in this rule to minimize the cost and paperwork burden to certifiers and certified operations as much as possible. We have permitted certifiers and certified operations to develop their own recordkeeping and reporting systems—so long as they conform to the needs of the program. For the most part, the paperwork and recordkeeping requirements for certified operations conform to the requirements that they presently face under existing certification programs. In order to minimize the cost to the industry of transitioning to a system where certifying agents are accredited (assuming that there will be a learning curve as agents familiarize themselves with the requirements of accreditation), we have waived the per-hour cost that USDA will charge to conduct an accreditation review for the first 18 months of the program.

(2) In the proposed rule, we requested comment on the benefits of an exemption for small certifiers similar to that for small producers. We received comments in opposition to such an exemption because commenters wanted to maintain documented verification of standards that is afforded by certification and accreditation. They felt that

exemptions weakened the organic system in its ability to assure consumers of products that meet a consistent standard. We concurred with this comment and have not developed an exemption for certifiers in the final rule.

Comments Rejected

(3) We received comments suggesting that, in order to lower the direct cost of accreditation to smaller certifier applicants, we should eliminate on-site visits during accreditation or extend the time beyond the initial on-site visit for a subsequent visit. Although eliminating the on-site visits would certainly lower the applicant's costs, we have not made the change to reduce or eliminate on-site visits. We did not see how USDA could make an informed decision about whether or not to continue to accredit a certifying agent without complete access to the relevant records documenting the agent's business practices. This can only be efficiently done through a site visit.

(4) We received numerous comments that the fees proposed by USDA will result in certification fees that are excessive for small farming operations. The commenters suggested that USDA impose fees on a sliding scale based on a farmer's income so as not to drive these farmers out of business and deprive consumers of the benefits of these operations. We received a similar comment to the Fees section of the proposed rule, and our response is the same. Although one of our top priorities is assisting the small farmer, AMS is primarily a user-fee-based Federal agency. We are aware that our accreditation fees will figure into the fees that certifiers charge their clients. However, the fee we will charge to accredit an applicant is based not on earning profits, but on recovery of costs. In addition, our waiver of the hourly service charges for accreditation during the first 18 months of the program should help to keep the cost of accreditation to certifying agents down. We believe the requirements that fees charged by a certifying agent must be reasonable and that certifiers must file a fee schedule for approval by the Administrator will help to keep costs under control. Since certifiers are required to provide their approved fee schedules to applicants for certification, the applicants will be able to base their selection of certifying agent on price if the applicants so choose. In addition, nothing in the regulations precludes certifying agents from pricing their services on a sliding scale so long as their fees are consistent and nondiscriminatory and are approved during the accreditation process.

(5) Other commenters were concerned that in the rule USDA neglects to establish "reasonable fees" annually for farm/site/wild crop production and handling operation certification. Commenters did not believe that a valid Regulatory Flexibility Act analysis could be made without the annual farm and handling operation fee projection. We have not established guidelines for what constitutes a "reasonable fee" in the final rule. Accredited certifying agents will be required to submit a proposed fee schedule as a part of their application. At that time, we will work with applicants for

accreditation to ensure that their fees are appropriate. In addition, certifying agents will be required to send a copy of their fee schedule to anyone who requests one. This will allow operations that wish to be certified to shop around and will provide a disincentive for accredited agents to price themselves out of the market.

3. Description of and an estimate of the number of small entities to which the rule will apply.

Small business size standards, Standard Industrial Code (SIC) (13 CFR part 121), are developed by an interagency group, published by the Office of Management and Budget, and used by the Small Business Administration (SBA) to identify small businesses. These standards represent the number of employees or annual receipts constituting the largest size that a for-profit enterprise (together with its affiliates) may be and remain eligible as a small business for various SBA and other Federal Government programs.

There are three categories of operations that contain small business entities that would be affected by this rule: Certifying agents, organic producers, and/or organic handlers. The term, "certifying agent," means the chief executive officer of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of a State, such official and any person (including private entities) who is accredited by the Secretary as a certifying agent for the purpose of certifying a farm or handling operation as a certified organic farm or handling operation.

According to the most complete data available to USDA's Agricultural Marketing Service (AMS), there are 49 certifying agents (36 private and 13 State) in the United States. More than half of the private and State certifying agents certify both producers and handlers, while the others certify only producers. Over three-fourths of private and State certifying agents each certify fewer than 150 producers and 20 handlers. The number of certifying agents has remained fairly stable, between 40 and 50, for some years, with entries and exits tending to offset each other. The NOP staff anticipates that, in addition to the 49 domestic certifying agents, 10 foreign certifying agents may seek accreditation during the initial phase of the program.

Small businesses in the agricultural services sector, such as certifying agents, include firms with average annual revenues of less than \$5 million (SIC Division A Major Group 7). Based on SBA's small business size standards for the agricultural services sector, it is not likely that many, if any, of the 49 domestic certifying agents have annual revenue greater than \$5 million. All private, nonprofit certifying agents would be considered small by SBA's standards. Based on anecdotal information, only a few private, for-profit, certifying agents might be categorized as large businesses. In addition, the 13 State certifying agents, although not exceeding the revenue threshold, would not be considered to be small entities under the Act as only government jurisdictions with populations under 50,000 are considered to

be small entities under section 601(5). Therefore, at least 30 certifying agents would qualify as a small business.

The term, "producer," means a person who engages in the business of growing or producing food or feed. It is more difficult to establish the number of organic producers. Organic farming was not distinguished from conventional agriculture in the 1997 Census of Agriculture. There are sources which give insight into the number of producers. The Organic Farming Research Foundation (OFRF), a California-based nonprofit organization, has conducted three nationwide surveys of certified organic producers from lists provided by cooperating certifying agents. The most recent survey applies to the 1997 production year (1). □ □ □ OFRF sent its 1997 survey to 4,638 names and received 1,192 responses. Because OFRF did not obtain lists from all certifying organizations or their chapters (55 out of a total of 64 identified entities provided lists), its list count is likely an understatement of the number of certified organic producers. Note that the estimated number of organic producers includes only certified organic farms. Comments filed in response to the first proposal and studies indicate that the total number of organic farms is higher.

Dunn has estimated the number of certified organic producers in the United States (2, 3) Dunn's 1995 work, a USDA study, estimated the number of certified producers at 4,060 in 1994; this estimate was used in the first proposal. Dunn's 1997 work reported 4,060 certified organic farms in 1994 and 4,856 in 1995.

Data collected by AMS indicate that the number of organic farmers increased about 12 percent per year during the period 1990 to 1994. OFRF survey efforts indicate that growth has continued, although it is not clear whether the growth rate has changed. Similarly, growth in retail sales, the addition of meat and poultry to organic production, and the possibility of increased exports suggest that the number of operations has continued to increase. Lacking an alternative estimate of the growth rate for the number of certified organic producers, we use the average growth rate of about 14 percent from Dunn's 1997 study. The true rate of growth could be higher or lower. Applying the 14-percent growth rate to Dunn's estimate of certified producers in 1995 gives an estimate of 8,200 organic producers for 1999.

An adjustment is needed to account for the number of producers who are practicing organic agriculture but who are not certified and who would be affected by this regulation. We assume that the number of organic but not certified producers in 1999 is about 4,000. This assumption is based on very limited information about the number of registered but not certified organic producers in California in 1995. Thus, the total number of certified organic producers used in assessing the impact of the rule is 12,176.

Producers with crop production (SIC Division A Major Group 1) and annual average revenues under \$500,000 are small businesses. Producers with livestock or animal specialties are also considered small if annual average revenues are under \$500,000 (SIC Division A Major Group 2),

with the exception of custom beef cattle feedlots and chicken eggs, which are considered small if annual average revenues are under \$1,500,000.

Based on SBA's small business size standards for producers, it is likely that almost all organic producers would be considered small. The OFRF survey asked for the producer's total gross organic farming income during 1997. Only 35 (less than 3 percent) of the survey respondents reported gross income greater than \$500,000, the SBA's cutoff between small and large businesses. Over 70 percent reported gross income of less than \$50,000. The OFRF survey does caution readers about potential survey "errors." It is particularly important to emphasize potential "non-response error"; that is, it is unknown if those who responded to the survey accurately represent the entire population of certified organic growers. Also, some producers combine organic and conventional production on the same operation, some with total sales that may exceed \$500,000. However, it is likely that a majority of organic producers would be considered small. We have estimated that there would be 12,176 producers certified in the first year and of those 97 percent, or 11,811, based on OFRF's survey results, would qualify as a small business.

The term, "handler," means any person engaged in the business of handling agricultural products, excluding final retailers of agricultural products that do not process agricultural products. Little information exists on the numbers of handlers and processors. USDA has estimated that there were 600 entities in this category in 1994. In California, there were 208 registered organic processed food firms in 1995 and 376 in 1999, a growth rate of 20 percent (4). We assume that this growth rate is applicable to the U.S. and project 2,077 certified handlers in 2001. This figure includes 100 livestock feed handlers who would become certified organic. Again, the rate of growth could be higher or lower.

In handling operations, a small business has fewer than 500 employees (SIC Division D Major Group 20). It is also likely that the vast majority of handlers would be considered small, based on SBA's small business size standards for handlers. Based on informal conversations with organic certifying agents, currently, about 25 (about 2 percent) of the estimated 1,250 organic handlers in 1999 had more than 500 employees. This includes firms that handle or process both organic and conventional foods. We have estimated that 2,077 handlers would be certified organic in the first year. Based on this information, 98 percent or 2,035 would qualify as a small business.

4. An estimate of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.

The reporting, recordkeeping, and compliance requirements of the rule will directly affect three sectors of the organic industry that contain small business entities: accredited certifying agents, organic

producers, and organic handlers. We have examined the requirements of the rule as it pertains to each of these entities, however several requirements to complete this Regulatory Flexibility Analysis (RFA) overlap with the Regulatory Impact Assessment (RIA) and the Paperwork Reduction Act (PRA) section. In order to avoid duplication, we combine some analyses as allowed in section 605(b) of the Act. This RFA provides information specific to small entities, while the RIA or PRA should be referred to for more detail. For example, the RFA requires an analysis of the rule's costs to small entities. The RIA provides an analysis of the benefits and costs of this regulation. This RFA uses the RIA information to estimate the impact on small entities. Likewise, the RFA requires a description of the projected reporting, recordkeeping, and other compliance requirements of the final rule. The PRA section estimates the reporting and recordkeeping (information collection) requirements that would be required by this rule from individuals, businesses, other private institutions, and State and local governments. The burden of these requirements is measured in terms of the amount of time required of program participants and its cost. This RFA uses the PRA information to estimate the burden on small entities.

Certifying Agents

We have identified 36 private certifying agents and 13 State programs providing certification. These 49 domestic entities are considered likely applicants during the first 12 months, as are an estimated 10 foreign certifying agents. An unknown number of new entrants to the certifying business may also apply. However, over the last 10 years, the number of certifying agents does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of U.S.-based certifying agents at about 40 to 50. Of the 49 domestic certifying agents, based on information discussed previously, we estimate that 30 of the 36 private certifying agents are small businesses.

The recordkeeping and paperwork requirements are outlined in the Paperwork Reduction Act section. The requirements for small and large certifying agents are identical. The recordkeeping and paperwork requirements for accreditation will be a new burden to most agents as the majority of them have not been accredited in the past. However, the actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Certifying agents that currently are active in the organic industry already perform most of these required administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. Because the rule does not require any particular system or technology, it does not discriminate against small businesses. The ability of an agent to carry out the paperwork and recordkeeping sections of the rule will be more dependant on the

administrative skill and capacity of their particular organization than their size. We did not receive significant comments about the paperwork requirements of the proposed rule that would indicate that they will be onerous for small certifying agents.

Certifying agents will be the front line in monitoring and ensuring that certified operations stay in compliance with the Act and the regulations. However, most of the compliance requirements, with the exception of some reporting requirements, are consistent with what certifiers are currently expected to do. Like the paperwork and reporting requirements, the additional costs to an agent will depend on how different their current practices are from the final regulation.

The final, and probably most significant, area in which certifying agents are affected by the rule is in the fees that they must pay for accreditation. Certifying agents will be assessed for the actual time and travel expenses necessary for the NOP to perform accreditation services, including initial accreditations, 5-year renewals of accreditation, review of annual reports, and changes to accreditation. Although the fees have not been set yet, we are using as a starting point the hourly fees that are charged for the voluntary, fee-for-service program provided by AMS to certification bodies requesting conformity assessment to the ISO Guide 65, "General Requirements for Bodies Operating Product Certification Systems." We expect that at the time the NOP's final rule is implemented, the fees will be approximately \$95 per hour with higher overtime and holiday rates. Certifying agents will also be charged for travel, per diem, and other related costs associated with accreditation. To ease the financial burden of accreditation during the 18 month transition period after the NOP has been implemented, USDA will not impose hourly charges on certifying agents. The direct costs for certifying agents to obtain accreditation will be limited to per diem and transportation costs to the site evaluation. Review of the certifying agent's annual report is anticipated to range from 2 to 8 hours at the ISO Guide 65 hourly rate. Also, if certifying agents wish to become accredited in additional areas for which they were not accredited previously, a site evaluation (with associated fees) will be necessary. Detail about the expected costs of accreditation can be found in the RIA.

Several factors will influence the amount of time needed to complete an accreditation audit. An operation in which documents are well organized and that has few nonconformities within the quality system will require less time for an audit than an organization in which documents are scattered and there are many nonconformities (7). Similarly, in a followup audit, operations that lack organization in their documents and that had a large number of nonconformities during previous audits will require a greater amount of time. The scope of a followup audit is to verify the correction of nonconformities and to evaluate the effectiveness of the corrections. Certifying agents are able to control these cost factors by making certain that documents are well organized and by educating themselves about quality systems.

The complexity of a certification agency's organization also will affect the time needed to complete an audit. An agency with a central office in which all certification activities take place will require less time for document review and site evaluation than a chapter organization or a business structured so that responsibility for making certification decisions is delegated outside of the central office. In the latter cases, the auditors' document review would require additional time and site evaluation that would extend from the central office to one or more of the chapters or to the site to which the certification decision making is delegated.

Other factors determine the amount of time needed to complete an accreditation audit. For an agency with numerous clients, auditors may need to spend more time reviewing client files or examining business operations than they would have to spend for a smaller agency. Audit of an agency with a large number of processor clients may require an extended amount of time to follow audit trails, confirm that organic ingredients remain segregated from nonorganic ingredients, and establish that foreign-produced ingredients originate from approved entities. Finally, the complexity of the agricultural practices certified could influence the amount of time necessary to complete an accreditation audit. An agency whose certification covers only producers who grow and harvest one crop per field per year, such as wheat or sugar beets, could quickly be audited. An agency whose producers grow several different crops per field per year or an agency that certifies producers of crops and livestock as well as handlers would require a greater amount of time.

All of these factors will affect both small and large certifying agents. A small certifying agent could be assumed to have a less complex organization or have fewer clients, and, thus, potentially less time would be necessary for review. However, other factors, such as the degree of paperwork organization or the complexity of the agricultural practices certified, may influence the time needed for review for any size of business.

Currently, relatively few certifying agents have third-party accreditation because accreditation of certifying agents is voluntary. Fetter reports that in a sample of 18 certification programs, selected to include six large, private programs, six smaller private programs, and six State programs, four programs were accredited and one had accreditation pending (8). All of these were large private certifying agents. Three of the certifying agents identified by Fetter as accredited requested ISO Guide 65 assessments by USDA and have been approved for selling organic products into the international market. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation because their documents are organized and they have fewer nonconformities.

It is expected that all certifying agents will set their fee schedule to recover costs for their certification services, including the costs of accreditation. The larger the number of clients per certifying agent, the more fixed costs can be spread out. It is possible,

however, that small certifying agents could be significantly affected by this final rule and may not be able to continue in business from a financial standpoint.

Costs to Producers and Handlers

The OFPA established a small farmer exemption from certification and submission of organic plans for small producers with a maximum of \$5,000 in gross sales of organic products. For purposes of the exemption, the OFPA defines a "small farmer" as those who sell no more than \$5,000 annually in value of agricultural products. In this rule, we have clarified that the exemption applies to producers and handlers who sell no more than \$5,000 annually in value of organic products (9). In addition, handling operations are exempt if they: Are a retail food establishment that handles organically produced agricultural products but does not process them; handles agricultural products that contain less than 70 percent organic ingredients by weight of finished product; or does not use the word, "organic," on any package panel other than the information panel if the agricultural product contains at least 70 percent organic ingredients by weight of finished product.

A handling operation or specific portion of a handling operation is excluded from certification if it handles packaged certified organic products that were enclosed in their packages or containers prior to being acquired and remain in the same package and are not otherwise processed by the handler, or it is a retail food establishment that processes or prepares on its own premises raw and ready-to-eat food from certified organic products.

According to the OFRF survey, 27 percent of currently certified farms that responded to the survey would fall under the producer exemption. This percentage does not take into account those organic farms that are not currently certified by a private or State certifying agent. A study of California organic farms found that, of all organic farms (10) in 1994-95, about 66 percent have revenues less than \$10,000 (11). If California is representative and the distribution within the sub-\$10,000 category is uniform, then a third of the farms would be classified as small for purposes of the statutory exemption with annual sales less than \$5,000. Based on the California study and the OFRF survey results, we estimate that between 25 and 33 percent of organic producers are small and would qualify for exemption from the certification requirements.

We have estimated that there are 4,801 small organic producers and 173 handlers that will be exempt from certification (this figure does not include excluded operations). These operations would be required to comply with the production and handling standards and labeling requirements set forth under the NOP. They do not have to meet the paperwork requirements of certification and they must only keep records that document compliance with the law for 3 years (rather than 5 for certified operations). We anticipate that this exemption will be used primarily by small market gardeners and hobbyists who grow and process produce and other agricultural products for sale at farmers

markets and roadside stands to consumers within their communities.

Exempt producers will be allowed to market their products as organically produced without being certified by a certifying agent. Products marketed by exempt producers cannot be represented as certified organic or display the USDA organic seal. Products produced or handled on an exempt operation may be identified as organic ingredients in a multiingredient product produced by the exempt operation, but they may not be identified as organic in a product processed by others. These limitations may discourage some small producers from seeking exemption, who instead may choose to become certified. In this case, the costs of certification would apply. The value associated with having organic certification may outweigh the costs of certification.

As with accredited certifying agents, the regulation will impose administrative costs on certified producers and handlers for reporting, recordkeeping, residue testing, and other compliance requirements. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that become certified only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices differ from the requirements of the final regulation. Projected reporting, recordkeeping, and other compliance requirements of certifying agents are discussed in greater detail in the PRA and the RIA. The only distinction made in the final rule between large and small entities for reporting, recordkeeping, and compliance is for operators who produce less than \$5000 per year in organic products as stated above.

As with the certifying agents, most of the concern this rule generated for small certified operations revolves around fees. Under this rule, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary and posted in a place accessible to the public. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent may only charge those fees that it has filed with the Secretary. Furthermore, the certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating the certification.

Currently, supply and demand for certification services determine the fees charged in most areas. Some States charge minimal fees for certification and instead subsidize operating costs from general revenues. According to separate studies by Fetter, and Graf and Lohr, the majority of certifying agents structure their fee schedules on a sliding scale based on a measure of size, usually represented by the client's gross sales of organic products but sometimes based on the acres operated. Some certifying agents

charge an hourly rate for inspection and audit services.

Graf and Lohr's study indicates that even small farms require significant time for the certification process, and this time does not increase proportionately as farm size increases. None of the existing certification programs mention costs for residue testing, which the NOP will require in the form of preharvest testing when there is reason to believe that agricultural products have come into contact with prohibited substances. Preharvest testing is expected to be infrequent. Certifiers will recover the costs of preharvest testing through explicit charges to the producer whose crop is tested or through a generally higher fee structure that spreads the expected costs of tests over all clients.

This rule imposes no requirements that would cause certifying agents that are presently using a sliding-scale type fee schedule to abandon their current fee system. Certifying agents could recover their net additional costs by increasing their flat-fee component, their incremental charges, or both. Because accreditations are renewed only every 5 years, certifying agents will have 5 years to recover their net new costs. Certifying agents who become accredited during the first year of the program would have fewer direct costs to recover because they will not be charged the application fee and hourly charges for accreditation services.

Those currently receiving voluntary certification will likely see a modest increase as the certifying agent passes on its cost incurred under the NOP. Those not currently receiving certification and producing over \$5,000 annually in organic products will be required to become certified, and they will incur the actual costs of certification.

Some States, such as Texas and Washington, charge producers and handlers nominal fees for certification, and it is possible that more States might provide certification services as the NOP is implemented. Other States, such as Minnesota, have cost-share programs to help offset costs for organic producers.

Conclusion

This rule will primarily affect small businesses. We have, therefore, attempted to make the paperwork, recordkeeping, and compliance provisions as flexible as possible without sacrificing the integrity of the program. We are not requiring specific technologies or practices and with the 18-month phase-in of the program we are attempting to give both certifying agents and certified operators an opportunity to adapt their current practices to conform with the rule. Because we have attempted to make the rule conform with existing industry standards, including ISO guide 65 for certification and ISO guide 61 for accreditation, the changes for most organizations and operations should be relatively straightforward.

The fees required for accreditation will be the most significant change faced by most operations—and this was apparent in the comments received. While we understand the concerns of the affected organizations, in order to administer an accreditation program, it is necessary that we recover our costs. We

are hoping that the elimination of the hourly charges in the first round of accreditation will help to alleviate some of this burden.

1. Organic Farming Research Foundation. 1999. Final Results of the Third Biennial National Organic Farmers' Survey. Santa Cruz, CA.

2. Dunn, Julie Anton. 1995. Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States. U.S. Department of Agriculture, Agricultural Marketing Service.

3. Dunn, Julie Anton. 1997. AgriSystems International Reports Certified Organic Production in the United States: Half a Decade of Growth. AgriSystems International: Wind Gap, PA.

4. California Department of Health Services (DHS). 1995. Report on the Registration of California Organic Processed Food Firms. Sacramento: State of California. September 1999 figures obtained via personal communication with California DHS.

5. Graf, Anita and Luanne Lohr. 1999. Analysis of certification program costs. Working Paper, Fund for Rural America project, Market Development for Organic Agriculture Products, Grant No. 97-36200-5.

6. During the first 18 months, site evaluation for initial accreditation will be conducted jointly by two reviewers. Two reviewers offers: (1) Anticipated faster turnaround; (2) different areas of expertise—one reviewer would come from the Quality Systems Certification Program audit staff and would be familiar with ISO Guide 65 verification, while the other reviewer would come from the NOP staff and would be familiar with the requirements of the program; and (3) consistency with the organic industry's desire to have reviewers from both areas of expertise during ISO Guide 65 assessments. AMS would consider sending one reviewer, rather than two, for the site evaluation of small certification agents if an individual possessing both reviewing skill and knowledge of the NOP is available. We anticipate only one reviewer would be required after the 18-month transition period.

7. Adequate advance notice will be given to certifying agents to allow them the opportunity to organize their records prior to the audit and minimize the costs of accreditation.

8. Fetter, Robert T. 1999. Economic Impacts of Alternative Scenarios of Organic Products Regulation. Senior Honors Thesis. University of Massachusetts, Amherst, MA.

9. We asked for comments on the first proposal as to whether the current statutory limitation of \$5,000 for exemption from certification should be raised to \$10,000 or to another amount and why such an increased monetary limitation for exemption from certification would be appropriate. Few commenters offered recommendations as to a maximum sales volume to exempt producers. Amounts ranged from \$2,000 to \$50,000, with a few suggesting \$10,000 and \$20,000 exemptions. These proposed exemption levels and justifications in comments received are not sufficiently consistent enough for us to recommend changing the statute requirement of the \$5,000 maximum sales volume exemption.

10. California State law requires organic farmers to register with the State. Certification is voluntary at the current time.

11. Klonsky, Karen, and Laura Tourte. 1998. Statistical Review of California's Organic Agriculture, 1992–95. Report prepared for the California Department of Food and Agriculture Organic Program. Cooperative Extension, Department of Agricultural Economics, University of California, Davis.

Appendix D—Executive Order 12988, Civil Justice Reform

Executive Order 12988, Civil Justice Reform, instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. The revised proposal was reviewed under this Executive Order. No comments were received on that review, and no additional related information has been obtained since then. This rule is not intended to have retroactive effect.

States and local jurisdictions are preempted under section 2115 of the Organic Foods Production Act (OFPA) (7 U.S.C. 6514) from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States also are preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this regulation would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an

expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The Act also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

Appendix E—Executive Order 13132, Federalism

This final rule has been reviewed under Executive Order 13132, Federalism. This Order requires that regulations that have federalism implications provide a federalism impact statement that: (1) Demonstrates the Agency consulted with the State and local officials before developing the final rule, (2) summarizes State concerns, (3) provides the Agency's position supporting the need for the regulation, and (4) describes how the concerns of State officials have been met. The Order indicates that, where National standards are required by Federal statutes, Agencies shall consult with appropriate State and local officials in developing those standards.

The Organic Foods Production Act (OFPA) of 1990 (7 U.S.C. 6501 *et seq.*) establishes national standards regarding the marketing of agricultural products as organically produced, assures consumers that organically produced products meet a consistent standard, and facilitates interstate commerce in fresh and processed food that is organically produced. There has been a great deal of support for this law and these regulations from the organic community.

OFPA and these regulations do preempt State statutes and regulations related to organic agriculture. OFPA establishes national standards regarding the marketing of agricultural products as organically produced, assures consumers that organically produced products meet a consistent standard, and facilitates interstate commerce in fresh and processed food that is organically produced. Currently, 32 States have organic statutes on their books and have implemented them to various degrees. However, the Act contemplates a significant role for the States and, in fact, envisions a partnership between the States and the Federal Government in meeting the requirements of the Statute. The Act allows the States to determine the degree to which they are involved in the organic program. States may choose to: (1) Carry out the requirements of the Act by establishing a State organic program (SOP) and becoming accredited to certify operations, (2) establish an SOP but utilize private accredited certifying agents, (3) become accredited to certify and operate under the National Organic Program (NOP) as implemented by the Secretary, or (4) not play an active role in the NOP. 7 U.S.C. 6507 provides that States may establish an SOP consistent with the national program. SOP's may contain more restrictive requirements than the NOP established by the Secretary of Agriculture. To be more restrictive, SOP's must: further the purposes of the Act, be consistent with

the Act, not discriminate against organic products of another State, and be approved by the Secretary.

Because implementation of OFPA will have a significant effect on many States' existing State statutes and programs, the U.S. Department of Agriculture (USDA) has reached out to States and actively sought their input throughout the entire process of developing the organic rule. On publication of the first proposal on December 16, 1997, an announcement and information packet summarizing the proposal was sent to more than 1,000 interested parties, including State governors and State department of agriculture secretaries, commissioners, or directors. Over a period of 6 years, numerous meetings were held to provide States an opportunity to provide information and feedback to the rule. In 1994, States were invited to participate in four public hearings held in Washington, DC; Rosemont, IL; Denver, CO; and Sacramento, CA, to gather information to guide development of standards for livestock products. States were also provided the opportunity to comment specifically on State issues at a National Organic Certifiers meeting held on July 21, 1995. They were invited to discuss accreditation issues at a meeting held on February 26, 1996. Following the publication of the first proposal, State and local jurisdictions had the opportunity to provide input at four listening sessions held in February and March 1998 in Austin, TX; Ames, IA; Seattle, WA; and New Brunswick, NJ. A meeting to discuss the role of States in the NOP was held in February 1999. A State organic certifiers meeting to discuss State issues was held at a March 2000 meeting with the National Association of State Organic Programs.

USDA also drew extensively on the expertise of States and the organic industry by working closely with the National Organic Standards Board. The Board met 12 times before publication of the proposed rule on December 16, 1997, and met five times during 1998 and 1999 and two times in 2000. States were invited to attend each of these meetings, and official State certifier representatives participated in Board deliberations in meetings held in July 1998, July 1999, and March 2000.

Public input sessions were held at each meeting to gather information from all interested persons, including State and local jurisdictions. NOP staff also received comments and consulted with States at public events. They made presentations, received comments, and consulted with States at local and regional organic conferences and workshops and at national and international organic and natural food shows. States were consulted in training sessions held for organic inspectors, as well as numerous question and answer sessions at speaking engagements of the Agricultural Marketing Service (AMS) Administrator, the NOP Program Manager, and NOP staff.

In addition, during August and September 2000, the Administrator and NOP staff engaged in extensive efforts to discuss the proposed rule. While many organizations declined opportunities for these briefings, AMS staff did meet with the National

Conference of State Legislatures (NCSL) and, at their request, in lieu of a meeting, provided information to the National Governor's Association (NGA). NGA and NCSL representatives stated they were aware of the development of the final rule but offered no comments during these consultations beyond those submitted by the individual States during the proposed rule's comment period. In addition, between August and October 2000, NOP staff had telephone or e-mail contact with the State organic program directors or other State department of agriculture representatives in 25 States to determine the scope and status of each State's organic program in the context of the issuance of the final rule. These State representatives stated that they were eagerly awaiting the publication of the final rule and had already begun adjusting their programs to conform with the March 2000 proposed rule in anticipation of the publication of the final rule. Finally, States have had the opportunity to comment on two proposed rules. More than 275,000 comments were received on the first proposal, and 40,000 on the second proposed rule—including extensive comments from twelve State departments of agriculture, one State legislator, two members of Congress, and the National Association of State Organic Programs.

Through this outreach and consultation process, States have both provided general feedback to the rule and expressed several specific concerns about how this rule will affect State programs. Overwhelmingly, States were extremely supportive of the March 2000 proposed rule. With a few exceptions, most notably who should bear the cost of enforcement of an SOP, States are supportive of the Federal legislation. We did not receive a single comment from a State that indicated that there should not be a national organic program.

The most prevalent issues they raised regarding the March 2000 proposed rule as to how this rule will affect organic programs in their States, along with USDA's response, are described below. We received no direct comments from States on the Federalism section in the proposed rule. Many of these concerns and others are addressed in more detail in the relevant sections of the rule.

Applicability

Regarding section 205.100(b), five States currently offer a "transition to organic" label for producers who are in the process of

becoming certified. Many of these States would like to continue to offer this label. However, OFPA does not authorize a "transition to organic" label. Although the States (or private certifiers) are free to come up with a different label for these farmers, they cannot utilize the term, organic, in any seal or labeling associated with the conversion period. There is no change in this provision from the proposed rule.

Accreditation

Regarding section 205.501(a), many States wanted the NOP to add an additional subsection to the Accreditation section requiring certifiers to prove that they can carry out a State's more restrictive standards in order to be accredited to certify in that State. AMS concurs with this suggestion and has added a new paragraph 205.502(a)(20) requiring the certifying agent to demonstrate its ability to comply with a State's additional requirements.

Regarding section 205.501(b), there was strong support by all of the States for the provision that States with SOP's are able to have higher standards than the NOP for operations within their State. However, there was not consensus among the States on the prohibition on private certifiers requiring more stringent standards.

Although most supported the prohibition on private certifiers imposing additional requirements as a condition of certification because they perceived that it lowered barriers to farmers and processors in their States, three States were strongly opposed to this provision. Because having a consistent national standard is one of the primary purposes of the legislation, there is no change in this provision from the proposed rule.

State Programs

There was general confusion about what is the difference between a State organic certification program and an SOP. In addition, some States wanted the scope of the NOP's oversight for State organic activities to be limited to certification. A State organic certification program is equivalent to a private or foreign certification program. States wishing to certify operations in their State must apply to the NOP for accreditation.

An SOP, on the other hand, requires the State to submit a plan to the NOP for approval to, in effect, administer the NOP within their State. Included in this is the

opportunity to include requirements that differ from the NOP. In creating an SOP, a State is also agreeing to take on enforcement activities that would otherwise be the responsibility of the NOP. One exception to a State's enforcement authority is that States with SOP's do not have jurisdiction over the accreditation of certifying agents and cannot revoke accreditation. They can investigate and report accreditation violations to the NOP. States with only an accredited certification program are only responsible for the level of enforcement that all accredited certifying agents, State, private, or foreign, are required to take on.

Regarding section 205.620(c), several States want broader language than "unique environmental conditions" to be the basis for a State to have the right to establish more restrictive requirements under an SOP. AMS does not concur. There is no change to this language in the final rule. It is the opinion of AMS that the current language is broad enough to cover the scope of more restrictive requirements as authorized by OFPA.

Regarding section 205.620(d), many States want it to be optional for States with SOP's to take on enforcement obligations; several want funding from USDA for enforcement activities. AMS does not concur with this change. AMS does not envision that participation under the NOP will impose additional fiscal costs on States with existing organic programs, other than the costs of accreditation.

Regarding section 205.621(b), several States commented that States with SOP's should not be required to publish proposed changes to their programs in the **Federal Register** for public comment. AMS concurs with this comment. This language was an oversight from the first proposed rule.

Fees

A few States commented that the proposed fees for accreditation could cost more than some States could afford to pay. They made some suggestions for reducing accreditation fees, ranging from no fees (a completely federally funded program) to charging reduced rates for travel or eliminating hourly charges. AMS has no plans to change the fee structure. As in the proposed rule, hourly charges for accreditation will be waived for all applicants in the first 18 months of the program to facilitate the conversion to a national accreditation system.

Compliance

Regarding section 205.665, several States wanted to know what their authority was to revoke the accreditation of private certifiers in their State who do not meet additional State standards under an SOP. An SOP's governing State official is authorized to review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in their State. If they discover a noncompliance, they shall send a written report to the NOP program manager. Because accreditation is a Federal license, States do not have the authority to revoke a certifying agent's accreditation. There is no change in this section from the proposed rule

Appeals

Regarding section 205.668(b), several State commenters want appeals from SOP's to go

to State district court rather than Federal district court. AMS disagrees. The Act provides that a final decision of the Secretary may be appealed to the U.S. District Court for the district in which the person is located. AMS considers an approved SOP to be the NOP for that State. As such, AMS considers the governing State official of such State program to be the equivalent of a representative of the Secretary for the purpose of the appeals procedures under the NOP. Because the final decision of the governing State official is considered the final decision of the Secretary, under the Act it is then appealable to the U.S. District Court, *not* the State district court.

Regarding section 205.680, State commenters want a process by which people who feel they were adversely affected by the organic program in a State with an SOP may appeal to the SOP's governing State official,

rather than the Administrator. AMS has amended the language in section 205.680 to clarify to whom an appeal is made under various situations. If persons believe that they were adversely affected by a decision made by the NOP Program Manager, they appeal to the Administrator. If they were adversely affected by a decision made by a certifying agent (State, private, or foreign), they appeal to the Administrator unless they are in a State with an SOP, in which case, they appeal to the SOP's governing State official. If persons believe that they were adversely affected by a decision made by a representative of an SOP, they appeal such decision to the SOP's governing State official or such official's designee.

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